Cervical Screening Manual

The Cervical Screening Manual

A Guide for Health Departments and Providers

Collaboration Partners:

Chronic Disease & Injury Section
Breast and Cervical Cancer Control Program
Women's & Children's Health Section
State Laboratory of Public Health

North Carolina Department of Health and Human Services
Division of Public Health

State of North Carolina
Department of Health and Human Services
Division of Public Health • N.C. Breast and Cervical Cancer Control Program
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Leah Devlin, DDS, MPH
State Health Director

MEMORANDUM

To: Local Health Directors
Attention: Nursing Directors/Supervisors

From: Leah Devlin, DDS, MPH
State Health Director

Date: July 1, 2008

Subject: Revised Edition (July 2008)
Cervical Screening Manual: A Guide for Health Departments and Providers

Enclosed is the revised edition of the Cervical Screening Manual: A Guide for Health Departments and Providers, July 2008. Please replace the previous manual, dated June 2004 with this edition.

Numerous references have been consulted to assure that current standards and guidance on care of patients with abnormal Pap tests are used. These references include the:

- American Cancer Society (ACS)
- U.S. Preventive Services Task Force (USPSTF)
- American College of Obstetricians and Gynecologists (ACOG)
- 2006 Consensus Guidelines for the Management of Women with Abnormal Cervical Cancer Screening Tests.

Revisions were made by the Division of Public Health through a collaborative effort of the Chronic Disease and Injury Section, the Women and Children's Health Section and the State Laboratory. The Division of Public Health supports these guidelines as a model for the care of patients at the local level. We hope this guide will enable you to develop written policies to better identify and control cervical cancer among women in North Carolina.

Leah Devlin, DDS, MPH

ACKNOWLEDGEMENTS

Cervical Screening Manual: A Guide for Health Departments and Providers
This guide was reviewed and revised through the collaborative efforts of representatives of the following Division of Public Health Sections:

Chronic Disease & Injury Section
Breast and Cervical Cancer Control Program
Women's & Children's Health Section
State Laboratory of Public Health

Members of the Revision Committee express deepest gratitude and appreciation to all of the individuals who worked toward the successful completion of the Guide.

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A Guide for Health Departments and Providers

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Overview

Overview

The incidence of cervical cancer has decreased significantly since the 1950s in large part because of early detection efforts via the Papanicolaou (Pap) test.[1] This cytologic staining procedure of cells from the uterine cervix is primarily for detection and diagnosis of cervical cancer and certain pre-malignant conditions. Since its introduction in 1948, the Pap test is credited with saving tens of thousands of women's lives and decreasing deaths from cervical cancer by more than 70 percent. Still, the American Cancer Society estimates that 10,100[2] new cases of invasive cervical cancer will be diagnosed nationwide in 2007, and that 3,700[3] women will die of the disease[4].

Detection and treatment of pre-cancerous cervical lesions identified by a Pap test can prevent cervical cancer from ever developing. Even when cervical cancer has already developed, a Pap test may detect it while still in an early stage. With prompt diagnostic follow-up and appropriate treatment, survival of early stage cervical cancer is almost 100 percent.[5]

The North Carolina *Cervical Screening Manual* for 2008 provides guidelines designed to support the goal of identifying pre-cancerous cervical lesions and early cervical cancer, and providing appropriate treatment that saves lives. Numerous references have been consulted to assure that current standards and guidance on care of patients with abnormal Pap tests are used. These references can be found in Appendix E.

The foundation of the Cervical Screening Manual is from:

2006 Consensus Guidelines for The Management of Women with Abnormal Cervical Cancer Screening Tests, Thomas C. Wright Jr, MD; L. Stewart Massad, MD; Charles J. Dunton, MD; Mark Spitzer, MD; Edward J. Wilkinson, MD; Diane Solomon, MD, for the 2006 American Society for Colposcopy and Cervical Pathology-sponsored Consensus Conference.

2006 and 2008 Consensus Guidelines Algorithms by American Society for Colposcopy and Cervical Pathology published by Elsevier

American Cancer Society

American College of Obstetricians & Gynecologists

U.S. Preventive Services Task Force (USPSTF)

The guidelines are supported by the North Carolina Department of Health and Human Services, Division of Public Health, as a model for the care of patients at the local level. The guidelines are not program-specific.

If local health care provider agency policy differs from these guidelines, the local health care provider agency will have written policies and protocols that are consistent with the clinical practice of their clinical providers and their referral resources.

It is important to recognize that these guidelines should never substitute for clinical judgment. Clinical judgment should always be used when applying a guideline to an individual patient because it is impossible to develop guidelines that apply to all situations.[6]

I. Patient Management and Follow-up of Pap Test Results

Patient Management and Follow-Up of Pap Test Results

A. Introduction

Local Policies

Local policies and procedures should be developed for patient management. The North Carolina Department of Health and Human Services, Division of Public Health's Cancer and Women's Health Branches, and the State Laboratory recommend this Guide to develop local policy.

Multiple Public Programs

The recommendations in this Guide are for all women regardless of the specific clinic where they are enrolled. When a patient is seen in several health care provider agency clinics, clinic staff should coordinate efforts to prevent duplication of unnecessary Pap tests.

Financial Assistance

The Cancer Assistance Unit (CAU), formerly the Cancer Control Program, is a part of the North Carolina Comprehensive Cancer Program. The Cancer Assistance Unit provides information on cancer-related resources, services, and financial assistance for men and women with all types of cancers. Cancer Assistance funds can cover medical care for eligible persons who need services for cancer diagnosis or cancer treatment and it can pay for inpatient, outpatient, or office/clinic services. See Appendix F for information.

For eligible patients diagnosed through the NC BCCCP, Breast and Cervical Cancer Medicaid (BCCM) may be another source of financial assistance for treatment and other medical needs during treatment. See Appendix F for information on BCCM.

Pap Tests are not a Substitute for Medical Judgment

Cervical Pap tests are screening tests meant to detect a variety of squamous epithelial lesions and neoplasias, including dysplasia, carcinoma-in-situ (CIS), and other types of neoplasia. Please note that a single negative Pap result (and occasionally multiple negative Pap results) does not rule out gynecologic neoplasia. The Pap test is a screening test. False negative tests may occur due to sampling problems, screening difficulties inherent in tests, or due to the subjective interpretative character of cytodiagnosis.

It is important to recognize that these guidelines should never substitute for clinical judgment. Clinical judgment should always be used when applying a guideline to an individual patient because it is impossible to develop guidelines that apply to all situations.[6]

Pap Results Requiring Follow-up

Any of the following abnormal findings should be reported to the physician consultant for the health care provider agency or managed according to local policies and procedures:

- Atypical Squamous Cells: Undetermined Significance (ASC-US)
- Atypical Squamous Cells: Cannot Exclude High-grade SIL (ASC-H)
- Low-grade Squamous Intraepithelial Lesion (LSIL). This category encompasses HPV infection and mild dysplasia.

- High-grade Squamous Intraepithelial Lesion (HSIL). This category encompasses moderate and severe dysplasia, as well as Carcinoma-in-situ (CIS).
- Squamous cell carcinoma
- Atypical glandular cells (AGC), including adenocarcinoma in situ (AIS) and adenocarcinoma
- Other malignant neoplasms

1. Reporting of Pap Test Results

The Bethesda System 2001

The Bethesda System 2001 (TBS 2001) updates the standard terminology for reporting Pap test findings. It has been the standard of reporting in North Carolina since October 1, 2002.[7] See Appendix A for a summary of reporting categories.

The major features of the 2001 system are the following:

- Specimen adequacy is reported as either "Satisfactory" or "Unsatisfactory" for interpretation. The former category of "Satisfactory but Limited by…" was eliminated. The Bethesda 2001 system further divides the unsatisfactory category into two sections:
  (1) Unsatisfactory rejected
  (2) Unsatisfactory examined (See Sections I.B.2 through I.B.8 for a more complete discussion of unsatisfactory Pap test results)
- Quality indicators, such as the presence or absence of endocervical or transformation zone component, or obscuring inflammation or blood, are reported on all cases in the narrative portion of the report.
- The category of Negative for Intraepithelial Lesion or Malignancy replaces the earlier category of Within Normal Limits. Specific other findings may also be listed, including:
  (1) Evidence of infection with specific organisms, or
  (2) Endometrial cells present in a woman over 40.[8]
- The category of Benign Cellular Changes was eliminated. It is now included as a descriptor only in the category of Negative for Intraepithelial Lesion or Malignancy.
- The finding of ASC (atypical squamous cells) is divided into two sub-categories:
  (1) ASC-US (atypical squamous cells of undetermined origin)
  (2) ASC-H (atypical squamous cells, cannot exclude high-grade lesion)
- LSIL (low-grade squamous intraepithelial lesion) is unchanged. It encompasses HPV changes and mild dysplasia (CIN I).
- HSIL (high-grade squamous intraepithelial lesion) is unchanged. It encompasses moderate and severe dysplasia and carcinoma in situ (CIN II, CIN III, and CIS).
- Squamous cell carcinoma remains unchanged.

- The category of AGC (atypical glandular cells) now divides atypical glandular cells by subtype. Atypical Glandular Cells (AGC) are reported as:
  (1) Atypical glandular cells
  (2) Atypical glandular cells, favor neoplasia
- Adenocarcinoma in situ and adenocarcinoma are also reported under Atypical Glandular Cells[9]

2. Who Needs to have a Pap Test and When to Screen

Expert Recommendations

Guidelines for cervical cancer screening have been issued by the American Cancer Society (ACS)[2] the U.S. Preventive Services Task Force (USPSTF)[10], and the American College of Obstetricians and Gynecologists (ACOG)[11]. In September 2006, the 2006 consensus guidelines for the management of women with abnormal cervical cancer screening tests was developed by a group of 146 experts representing 29 organizations (including ACS, Center for Disease Control and Prevention, and ACOG)[12].

When to Begin Screening:

Pap test screening should begin approximately three years after first sexual intercourse or by age 21, whichever occurs first.

When to Discontinue Screening:

Screening may be discontinued in older women if they have had adequate recent screening with normal Pap tests and are not otherwise at high risk for cervical cancer. Local policies may refer to specific guidelines which differ slightly in their recommendations. (See additional resources, article 3)

ACS: Women who are age 70 and older with an intact cervix and have had three or more documented, consecutive, technically satisfactory normal or negative Pap tests within the 10-year period prior to age 70 may elect to cease screening. Women with a history of cervical cancer, in utero exposure to diethylstilbestrol (DES), or who are immunocompromised (including those who test positive for the human immunodeficiency virus) should continue cervical cancer screening for as long as they are in reasonably good health.[2]

USPSTF: The USPSTF recommends against routinely screening women older than age 65 for cervical cancer if they have had adequate recent screening with normal Pap tests and are not otherwise at high risk for cervical cancer.[4]

ACOG: Does not recommend an upper limit.[11]

Screening After Hysterectomy:

Screening may be discontinued in women who have had a hysterectomy for benign reasons. Local policies may refer to specific guidelines which differ slightly in their recommendations.

ACS: Cervical cancer screening is not indicated for women who have had a total hysterectomy (with removal of the cervix) for benign gynecologic disease. However, women who have had a subtotal hysterectomy should be screened according to the recommendations for women at average risk. Women with a history of cervical intraepithelial neoplasia (CIN) 2,3 who have undergone hysterectomy, or for whom it is not possible to document the absence of CIN 2,3 as an indication for hysterectomy, should be screened until three documented, consecutive, technically satisfactory normal/negative cervical cytology results and no abnormal/positive cytology results within a 10-year period are achieved. Women with a history of in utero diethylstilbestrol (DES) exposure or a history of cervical carcinoma should continue screening after hysterectomy for as long as they are in reasonably good health and do not have a life-limiting chronic condition. (See Additional Resources, article 3)

ACOG: Women who have had a total hysterectomy and have no prior history of high-grade CIN may discontinue screening. Women who have had a hysterectomy and have a history of CIN 2 or CIN 3 – or in whom a negative history cannot be documented – should continue to be screened annually until three consecutive satisfactory negative cervical cytology results are obtained. Routine screening may then be discontinued. A woman who has had three, consecutive, satisfactory negative examinations following treatment for CIN 2 or CIN 3 before she had a hysterectomy also may discontinue screening.[11]

USPSTF: The USPSTF recommends against routine Pap test screening in women who have had a total hysterectomy for benign disease.[4]

NC BCCCP: NC BCCCP funds may not be used to pay for cervical cancer screening in a woman who has had a total hysterectomy, unless the hysterectomy was performed due to cervical neoplasia. NC BCCCP funds can be used to pay for an initial pelvic examination to determine if a woman has a cervix, but may not be used to pay for follow-up pelvic examinations in the absence of a Pap test, colposcopy or biopsy. NC BCCCP funds may be used to pay for Pap test screening for women who have had a supracervical hysterectomy and have an intact cervix.[13]

Recommended Screening Intervals

- After a woman has had three or more consecutive, satisfactory, normal biennial examinations, the Pap test may be performed less frequently at the discretion of her physician, usually every 2-3 years. (See below.)
- **ACOG** and **ACS** recommend annual screening for women younger than 30 if a conventional cytologic smear is used. If liquid-based technology is used, ACS recommends screening may be performed every two years until age 30; ACOG does not make this distinction based on the technology used. Women aged 30 years and older who are at average risk and have had three consecutive negative Pap tests may be screened every 2-3 years with the addition of the HPV DNA test. (The NC State Lab does not cover HPV DNA testing as an adjunct to screening, nor does NC BCCCP or Title X cover this testing).
- **USPSTF** did not find direct evidence that annual screening achieves better outcomes than screening every three years.[4]

- It is especially important to screen women who have never been screened or are rarely screened, since these women are at greatest risk of developing cervical cancer.[14]

Maternal Health Patients

Pap test as indicated according to ACOG, ACS and USPSTF guidelines.

Family Planning (Title X) Patients

Pap tests as indicated by history, physical, contraceptive method, previous lab tests, and/or ACOG/ACS/USPSTF guidelines.

STI Clinic Patients

If a woman has not had a Pap test in the previous 12 months that is documented in the clinical record, she should be offered a Pap test as part of routine clinical evaluation.

N.C. Breast And Cervical Cancer Control Program (NC BCCCP) Patients

The North Carolina Breast and Cervical Cancer Control Program (NC BCCCP) has specific guidelines for the frequency of Pap test screening when results are negative for intraepithelial lesion or malignancy. See Appendix C for a summary of the policy.

3. Adequacy/Quality of the Pap Test Specimen

The Bethesda System for reporting of Pap tests requires the cytotechnologist to report on whether the specimen is adequate for meaningful evaluation.

PAP Test Collection Technique

A good Pap test specimen samples cells from the squamocolumnar junction (transformation zone) of the cervix. When a Pap test is correctly obtained from a pre-menopausal non-pregnant woman with a cervix, the specimen will usually contain both endocervical cells and cells from the ectocervix.

Possible causes of Pap tests lacking endocervical cells include:

- The transformation zone was not well sampled.
- The patient is pregnant.
- The transformation zone has receded into the canal in a woman who is post-menopausal.
- The transformation zone will be absent if the woman has had a hysterectomy and the cervix was removed. Endocervical cells may also be absent in Pap tests from women who have had cervical conization or LEEP procedures.
- The sampling device was not rinsed properly into the vial.

Bethesda 2001 Reporting

Cervical cytology reports that use the Bethesda System of reporting will describe specimen adequacy in one of two categories:

1. Satisfactory for evaluation. These specimens are of good quality and they usually contain some endocervical cells. However, the narrative portion of the report may describe some quality concerns such as:

   a. Absence of endocervical cells
   b. Slightly more than 5,000 cells on the slide
   c. Cells partially obscured by elements such as blood cells or inflammatory exudate
   d. Other limitations described in the report.

2. Unsatisfactory for evaluation. This category is divided into two sub-categories:

   a. Unsatisfactory rejected. The cytologist did not attempt to evaluate these specimens. Possible reasons are:
      (1) Unlabeled specimens
      (2) Names on the specimen and on the form do not match

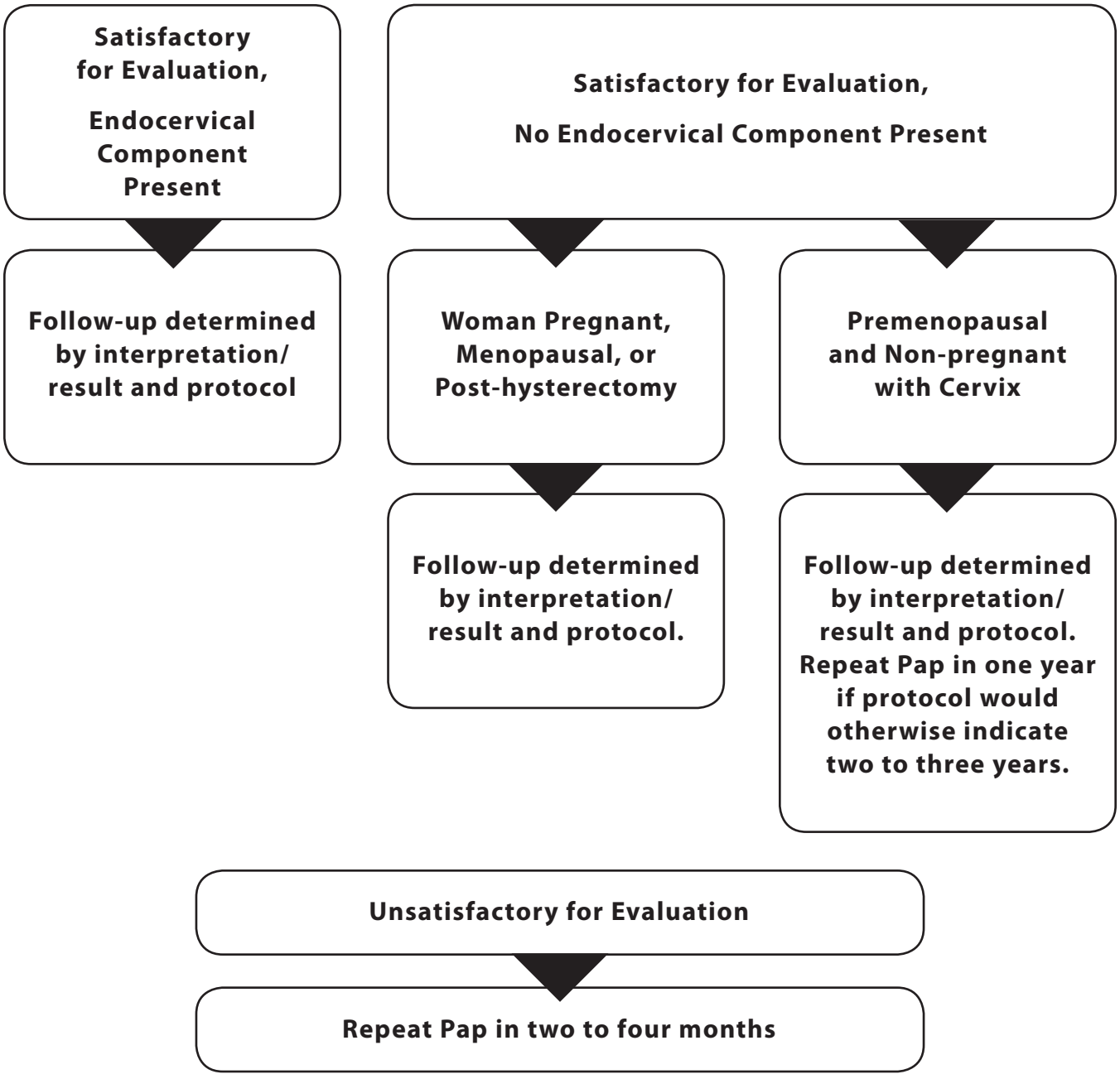
   b. Unsatisfactory examined. The cytologist attempted to evaluate these specimens, but was not able to arrive at an interpretation/result. Possible reasons are:
      (1) Insufficient cells (less than 5,000 cells on the slide)
      (2) Cells obscured by too much blood or inflammatory exudate

NOTE: If abnormalities are found on an otherwise unsatisfactory specimen, it will, by definition, be considered satisfactory for interpretation.[11]

Unsatisfactory Pap tests in premenopausal women who have a cervix should be repeated in two to four months[15] allowing sufficient time for the cervix to repair itself from the previous specimen collection.

The presence of the endocervical component (endocervical cells and/or metaplastic cells and/or cervical mucus with endocervical cells) in the Pap test indicates that the squamocolumnar junction (transformation zone) has been sampled. The endocervical component should be present in the Pap test collected from most premenopausal non-pregnant patients with a cervix; however, it is not necessary to re-sample before one year if previous Pap test findings have been negative. **It is not uncommon for the endocervical component to be absent in a Pap test from pregnant, post-hysterectomy and post-menopausal women, as well as those women who have had cervical conization and LEEP procedures.**[16]

Specimen Adequacy Algorithm



NOTE: There are rare instances when endocervical cells will never be obtained.

B. Management Protocols

The following pages describe appropriate management when Pap test results indicate one of the following Bethesda System categories:

1. Negative for Intraepithelial Lesions or Malignancy
2. ASC-US (Atypical Squamous Cells of Undetermined Significance)
3. LSIL (Low-grade Squamous Intraepithelial Lesion), including HPV and mild dysplasia/CIN I
4. ASC-H (Atypical Squamous Cells, cannot exclude high-grade lesion)
5. HSIL (High-grade Squamous Intraepithelial Lesion), including moderate to severe dysplasia/CIN 2,3 and Carcinoma in situ/CIS
6. Squamous cell carcinomas
7. AGC (Abnormal Glandular Cells), including

a. Atypical glandular cells

b. Endocervical carcinoma

c. Endocervical adenocarcinoma in situ

d. Endometrial adenocarcinoma

e. Extrauterine adenocarcinoma

f. Adenocarcinoma, not otherwise specified (NOS)

8. Other malignant neoplasms

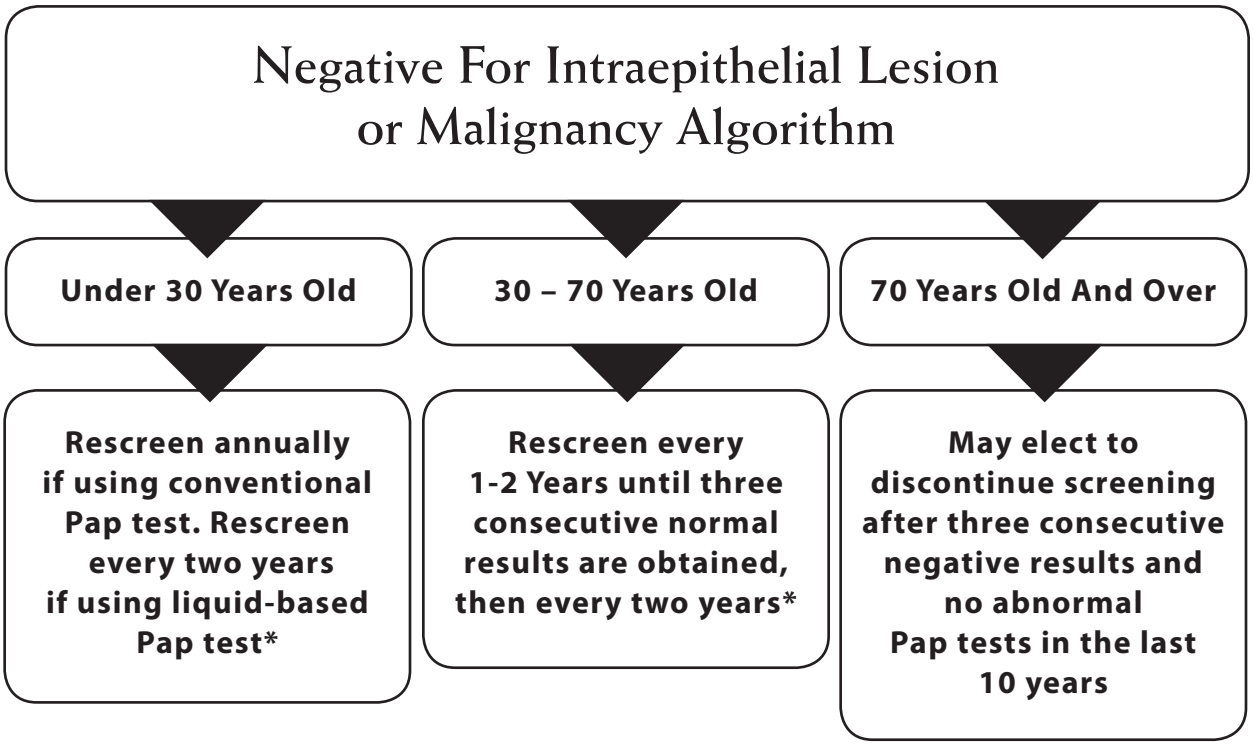
1. Negative For Intrapethelial Lesion or Malignancy

Patient Notification

Notify the patient of normal Pap test results according to local policy.

Patient Education

Instruct your patient regarding the importance of returning for a Pap test at appropriate intervals, or if she notices symptoms of any gynecologic problems.



Appropriate intervals for routine screening are determined by each individual woman's risk status. See page I-4 for **Recommended Screening Intervals**.

* Algorithm is based on American Cancer Society Recommendations for screening intervals for women at average risk for cervical cancer. Women who are at high risk should continue to be screened annually. High-risk women are those who:

- Are positive for HIV infection
- Are immunosuppressed, such as those receiving renal transplant
- Were exposed to diethylstilbestrol (DES) in utero

See Appendix C for NC BCCCP policy.

Non-Neoplastic Comments on Negative Results

Cytologic findings not considered abnormal, but which nonetheless may be of concern, are noted on the Pap test report. These may include:

- Infection, changes or organisms consistent with
  (1) Trichomonas vaginalis
  (2) Candida species
  (3) Herpes simplex virus
  (4) Actinomyces
  (5) Bacterial vaginosis
- Other non-neoplastic findings, such as endometrial cells present in a woman over 40 years old.[12]
- Reactive cellular changes, such as those associated with:
  (1) Inflammation or repair (including hyperkeratosis)
  (2) Radiation
  (3) Intrauterine contraceptive device
  (4) Atrophy

Do not repeat a Pap test for any of these findings, unless the specimen was unsatisfactory for evaluation. However, it is appropriate to address the cause of the findings.

INFECTION Refer to local health care provider agency protocols for treatment of infection or inflammation.

2. ASC-US (Atypical Squamous Cells of Undetermined Significance)

Atypical squamous cells (ASC) is a category the cytology lab uses to describe cells that are not quite normal, but do not meet criteria to be classified as dysplastic or neoplastic. The category is subdivided into Atypical Squamous Cells of Undetermined Significance (ASC-US) and Atypical Squamous Cells, cannot exclude HSIL (ASC-H). This section deals with ASC-US. For a discussion of ASC-H, see page I-19.

ASC-US findings often regress spontaneously to normal, but occasionally they will progress to high-grade lesions. For this reason, appropriate management of ASC-US remains somewhat controversial. The following guidelines are based on the 2006 Consensus Conference for the Management of Women with Abnormal Screening Tests.[12]

Patient Notification and Education

Notify the patient of Pap tests according to local policy. You will want to reassure her that a Pap result of ASC-US does not mean she has cancer. It may go back to normal on its own, but there is a slight chance it could progress to cancer. For this reason it is important to monitor her Pap tests closely. She may need to have additional testing as well.

Clinical Management

There are three options for management of women with ASC-US results.

Option 1: Refer for reflex high-risk HPV DNA testing. This procedure uses the original liquid-based Pap specimen to test for high-risk types of HPV DNA. If results are negative, repeat Pap test in one year. If results are positive for high-risk HPV, refer for colposcopy. The FDA requires HPV testing from the original vial be done within 3 weeks of collection, so the lab must be notified to save the vial for testing.

Option 2: Repeat Pap test in 6 months. If results are negative, repeat again in 6 months and, if still negative, return to routine screening. If either repeat Pap test results are ASC-US or worse, refer for colposcopy.

Option 3: Refer directly for colposcopy.

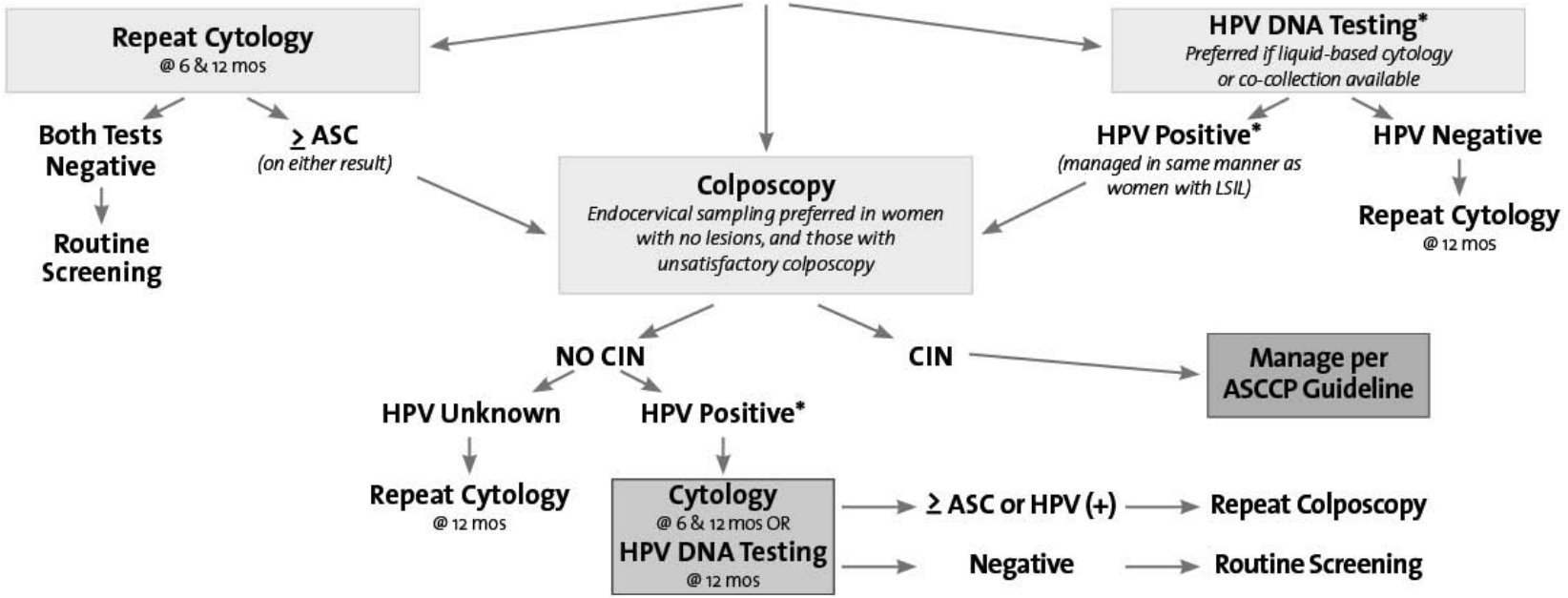
Special Circumstances

Adolescent clients. Annual pap testing is recommended for adolescents with ASC-US or worse. Those with HSIL at the 12 month follow-up and those with ASC-US or worse at the 24 month follow-up should both be referred for colposcopy.

Pregnant women. Pregnant women with ASC-US should be managed in the same manner as non-pregnant women with ASC-US.

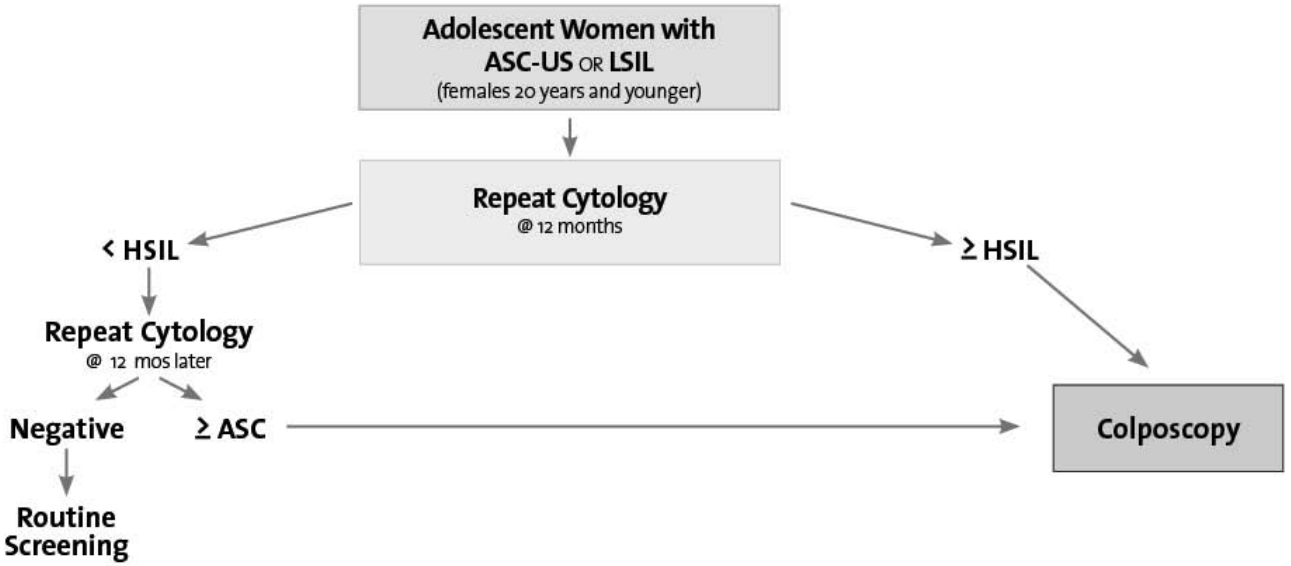
Atypical Squamous Cells of Undetermined Significance Algorithms – Refer to ASCCP Published Algorithms[18]

Management of Women with Atypical Squamous Cells of Undetermined Significance (ASC-US)



*Test only for high-risk (oncogenic) types of HPV

Management of Adolescent Women with Either Atypical Squamous Cells of Undetermined Significance (ASC-US) or Low-grade Squamous Intraepithelial Lesion (LSIL)



3. Low-Grade Squamous Intraepithelial Lesion (LSIL)

Patient Notification and Education

Notify the patient and counsel regarding the seriousness of the Pap test report, and the need to follow the recommendations of the health care provider. Document your actions. Additional evaluation is necessary.

Clinical Management

A result of LSIL is a good indicator of HPV infection.[12] Colposcopy is recommended for women with LSIL Pap test results except in special circumstances (adolescents and pregnant women). If the colposcopy examination is satisfactory and a transformation zone lesion is identified, it is also acceptable to obtain an endocervical sample. If no lesion is identified or the colposcopic examination is unsatisfactory, endocervical sampling is preferred.

- Since most patients with this Pap test finding require colposcopy, the health care provider agency should assure that referral is for colposcopic evaluation and treatment. A DHHS computer-generated Pap Test Follow up Form (DHHS 1011) will be sent to the health care provider agency for those patients needing follow up (See Section III "Instruction for Form Usage" on the DHHS 1011.)
- If biopsy confirms CIN 2,3 refer for treatment promptly.[19]
- If biopsy does not confirm CIN 2,3 there are two management options:
  Option 1 – Repeat Pap test at 6 and 12 months. If both results are negative, return to routine screening. If results are ASC-US or worse, repeat colposcopy.
  Option 2 – Refer for high-risk HPV DNA testing in 12 months. If HPV results are negative, return to routine screening. If testing is positive for high-risk HPV DNA, repeat colposcopy.
- A DHHS 1011(Cancer Screening Follow up Report) will be sent to the health care provider agency when the Pap result is a second consecutive atypia, HPV, or more significant findings/changes.

Special Circumstances

Postmenopausal patient with LSIL.

There are three options for management of post-menopausal women with LSIL results:

- **Option 1 – Repeat Pap test at 6 and 12 months.** If both results are negative, return to routine screening. If results of either short term Pap test are ASC-US or worse, refer for colposcopy.
- **Option 2 – Refer for reflex high-risk HPV DNA testing.** This procedure uses the original liquid based Pap specimen to test for high-risk types of HPV DNA. If results are negative, repeat Pap in 12 months. If results are positive for high-risk HPV DNA, refer for colposcopy.
- **Option 3 – Refer for colposcopy.**

Adolescents (<20 years old) with LSIL.

Repeat Pap test in 12 months. If negative, repeat again in 12 more months, and if still negative, return to routine screening. If results of the 12 month Pap test are HSIL or if the results of the 24 month Pap test are ASC-US or worse, refer for colposcopy. HPV DNA testing is inappropriate for adolescents with LSIL.

Pregnant women with LSIL.

There are two options for management of non-adolescent pregnant women with LSIL results:

- **Option 1 (preferred) – Refer for colposcopy.** Endocervical curettage is unacceptable. If no CIN 2,3 lesion is identified, follow up postpartum. If CIN 2,3 is found, manage per guidelines.[6]
- **Option 2 – Defer for colposcopy until six weeks postpartum.**

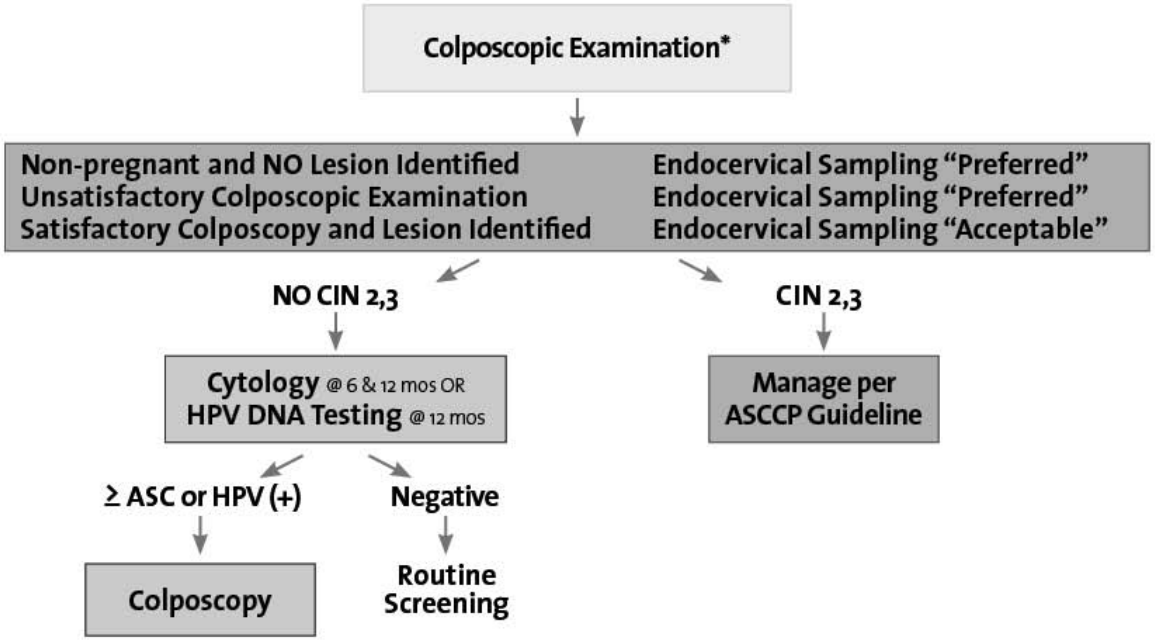
Low-grade Squamous Intraepithelial Lesion (LSIL) Algorithm

Pregnant Women with Low-grade Squamous Intraepithelial Lesion (LSIL) Algorithm

Adolescent Women with Either Atypical Squamomus Cells of Undetermined Significance (ASC-US) or Low-grade Squamous Intraepithelial Lesion (LSIL) Algorithm

Refer to ASCCP Published Algorithms[18]

Management of Women with Low-grade Squamous Intraepithelial Lesion (LSIL) *

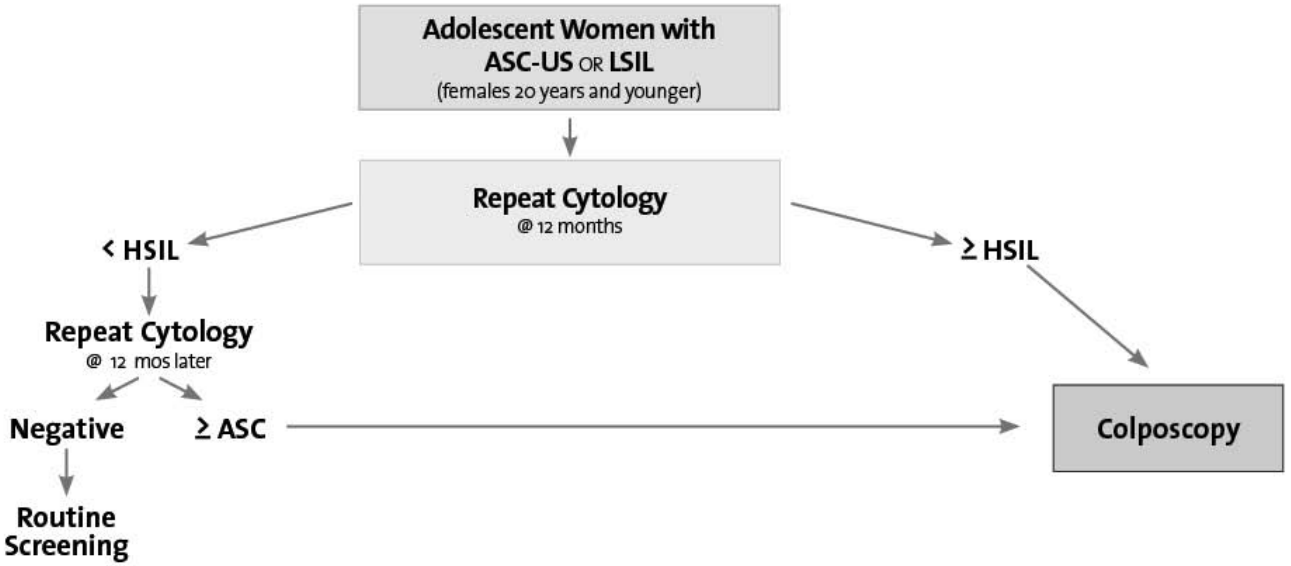


Management options may vary if the woman is pregnant, postmenopausal, or an adolescent - (see text)

Management of Pregnant Women with Low-grade Squamous Intraepithelial Lesion (LSIL)

^ In women with no cytological, histological, or colposcopically suspected CIN 2,3 or cancer

Management of Adolescent Women with Either Atypical Squamous Cells of Undetermined Significance (ASC-US) or Low-grade Squamous Intraepithelial Lesion (LSIL)



4. ASC-H (Atypical Squamous Cells – Cannot Exclude HSIL)

Atypical squamous cells (ASC) is a category the cytology lab uses to describe cells that are not quite normal, but do not meet criteria to be classified as dysplastic or neoplastic. The category is subdivided into Atypical Squamous Cells of Undetermined Significance (ASC-US) and Atypical Squamous Cells cannot exclude HSIL (ASC-H). This section deals with ASC-H. For a discussion of ASC-US, see page I-11.

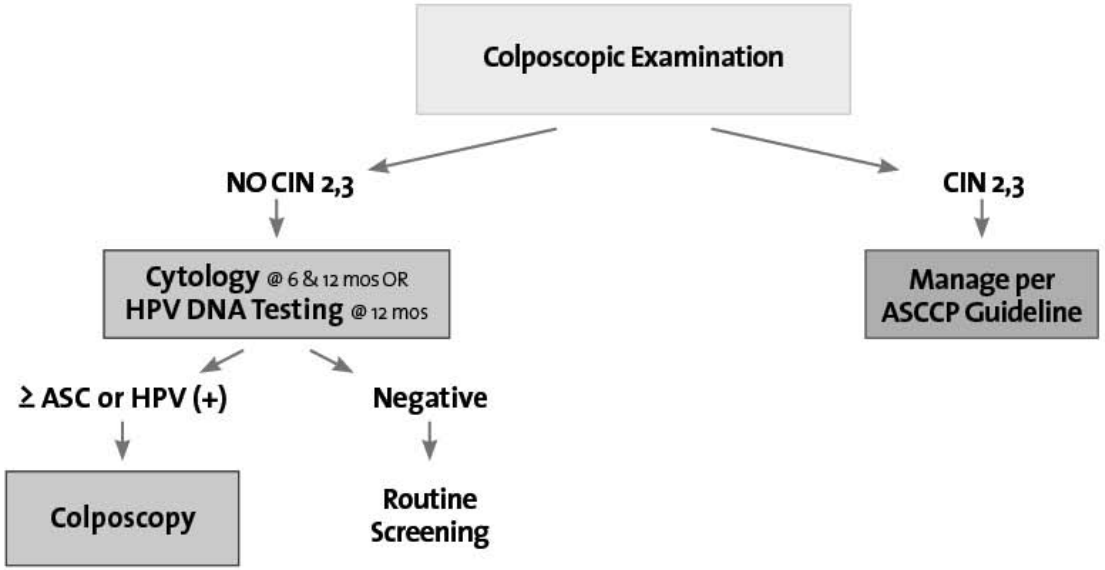
Patient Notification and Education

Notify the patient and counsel regarding the potential seriousness of the Pap test report, and the need to follow the recommendations of the health care provider. Document your actions. Additional evaluation is necessary.

Clinical Management

- Refer the patient to a Qualified Health Care Provider (QHCP)[20] for medical follow-up for colposcopy and treatment
- Since patients with this Pap test finding all require colposcopy, the health care provider agency should assure that referral is for colposcopic evaluation and treatment. A DHHS computer-generated Pap Test Follow-up Form (DHHS 1011) will be sent to the health care provider agency for those patients needing follow-up. (See **Section III** "Instruction for Form Usage" on the DHHS 1011.)
- If biopsy confirms CIN 2,3, refer for treatment promptly[19]
- If biopsy does not confirm CIN 2,3, the QHCP should review the referral cytology, colposcopic findings and all biopsies to determine if the cytology interpretation should be revised
  a. If the review results in a changed interpretation, manage according to revised result
  b. If a cytologic interpretation of ASC-H is upheld, there are two options:
     (1) Repeat Pap test in 6 months and 12 months, or
     (2) Follow with HPV DNA testing in12 months
  c. If pap test ≥ ASC or HPV positive, then repeat colposcopy. If negative, then return to routine screening.

Management of Women with Atypical Squamous Cells: Cannot Exclude High-grade SIL (ASC - H)



ASCCP

5. High-Grade Squamous Intraepithelial Lesion (HGSIL or HSIL)

HSIL is a serious finding. 70-75% of women with an HSIL Pap test will have a biopsy-confirmed CIN 2, 3 and 1-2% will have invasive cervical cancer.

Patient Notification and Education

Notify the patient and counsel regarding the seriousness of the Pap test report, and seek prompt medical care. Document your actions. Additional evaluation is necessary.

Clinical Management

HSIL should always be referred for colposcopy, diagnosis and treatment. Do not repeat Pap test: Refer patient.

- Refer the patient to a Qualified Health Care Provider (QHCP)[20] for medical follow-up for colposcopy and treatment
- Since patients with this Pap test finding all require colposcopy, the health care provider agency should assure that referral is for colposcopic evaluation and treatment. A DHHS computer-generated Pap Test Follow-up Form (DHHS 1011) will be sent to the health care provider agency for those patients needing follow-up. (See **Section III** "Instruction for Form Usage" on the DHHS 1011.)
- The State Lab gives notification of HSIL Pap results. CLIA has indicated this is a critical value report. See Appendix B for instructions.
- Treatment and follow-up is individualized, as directed by the QHCP

Note: If colposcopy was not completed, the patient should be advised about the necessity of this procedure.

Special Circumstances

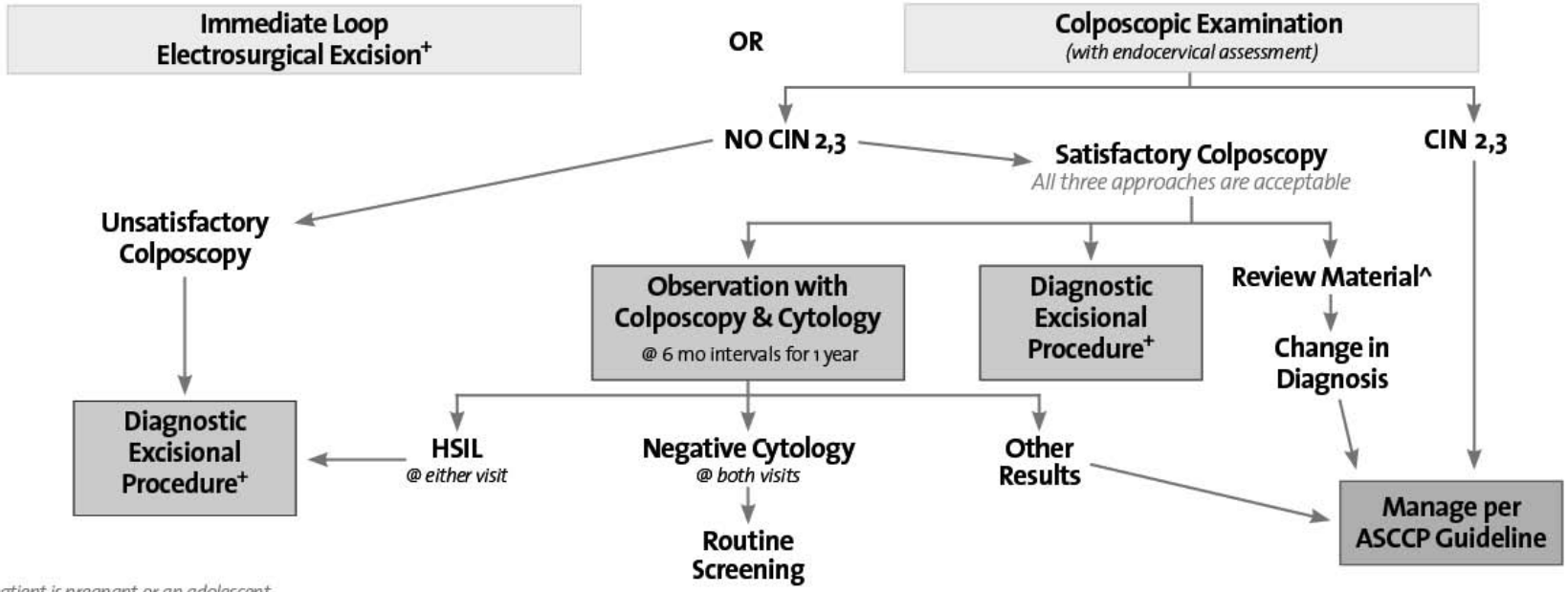
Pregnant women with HSIL or LSIL.

- Colposcopy of women who are pregnant should be conducted by clinicians who are experienced in the evaluation of colposcopic changes associated with pregnancy
- Biopsy of lesions suspicious for high-grade disease or cancer is preferred. Biopsy of other lesions is acceptable.
- Endocervical curettage (ECC) is unacceptable in pregnant women
- Unsatisfactory colposcopy should be repeated in 6-12 weeks
- Unless invasive cancer is identified, treatment (including LEEP) is unacceptable
- Re-evaluation should be completed after six weeks postpartum

Adolescents (≤ 20 years old)with HSIL

- In adolescents with HSIL, colposcopy is recommended. Immediate loop electrosurgical excision (i.e., "see and treat") is unacceptable in adolescent women.
- If biopsy does not confirm CIN 2,3 in an adolescent woman, observation with cytology and colposcopy at six months intervals for up to 24 months.
- If during follow-up a high-grade colposcopic lesion is identified or HSIL cytology persists for one year, biopsy is recommended.
- If HSIL persists for 24 months without identification of CIN 2,3 a diagnostic excisional procedure is recommended.
- After 2 consecutive negative cytology results, adolescents without a colposcopic abnormality can return to routine cytological screening.

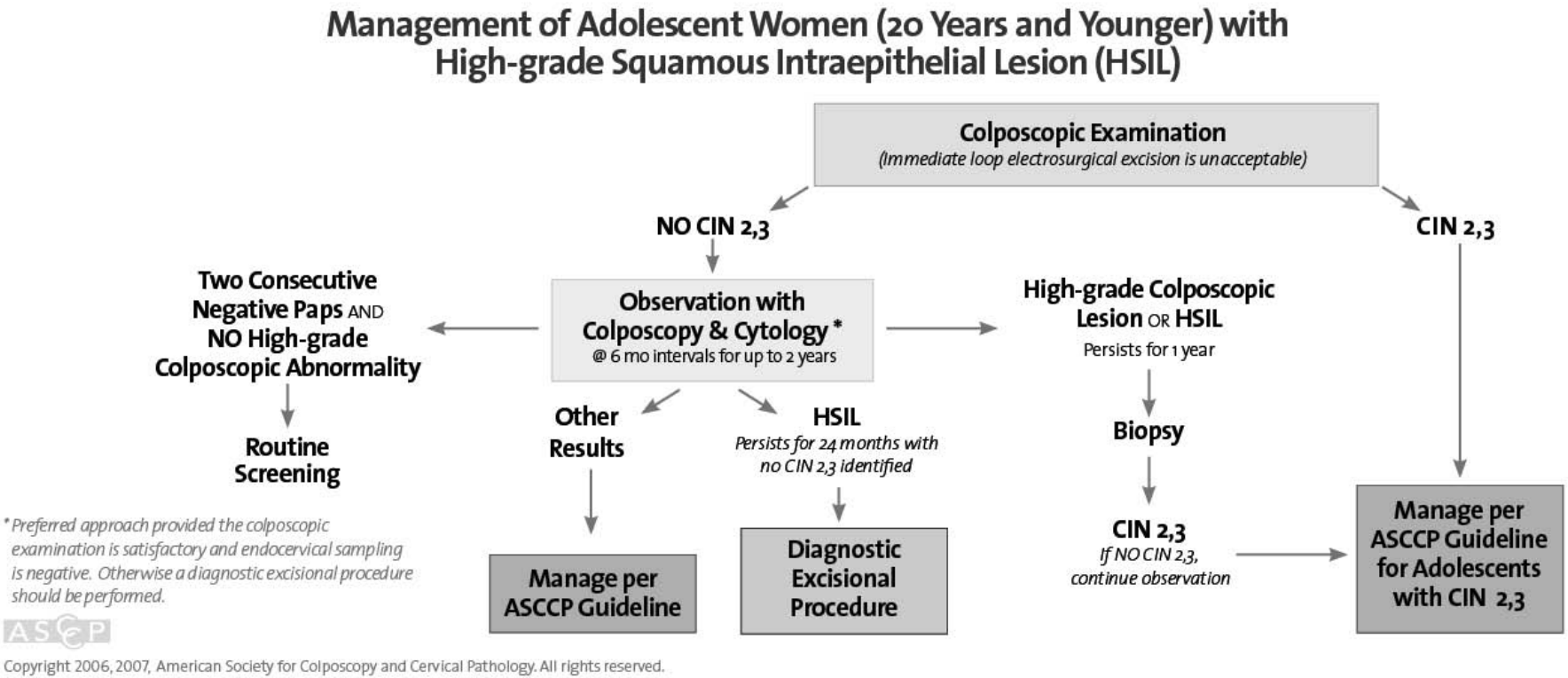
Management of Women with High-grade Squamous Intraepithelial Lesion (HSIL) *



+ Not if patient is pregnant or an adolescent

^ Includes referral cytology, colposcopic findings, and all biopsies

* Management options may vary if the woman is pregnant, postmenopausal, or an adolescent



Refer to ASCCP Published Algorithms[18]

6. Squamous Cell Carcinoma

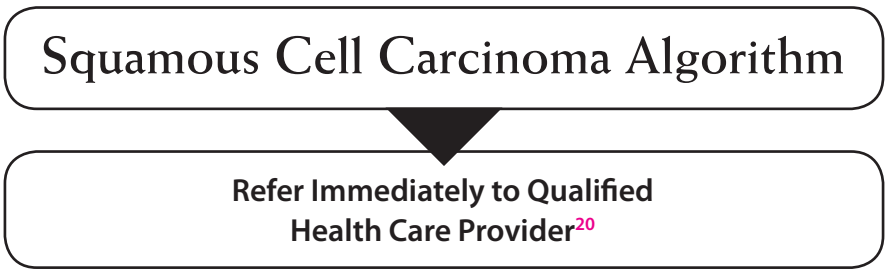
Squamous cell carcinoma is a serious finding on a Pap test. It is regarded as strongly suspicious for malignancy.

Patient Notification and Education

Notify and counsel the patient regarding the seriousness of the Pap test report and the need for immediate medical care. Document your actions. Additional evaluation is necessary.

Clinical Management

- Squamous cell carcinoma is regarded as strongly suspicious for malignancy and warrants a pathologic diagnosis. This requires a tissue sample, which is usually obtained through colposcopy with directed biopsy or LEEP.
- **IMMEDIATE** referral must be made for medical follow-up to a Qualified Healthcare Provider (QHCP).[20]
- Since patients with this Pap test finding all require colposcopy, the health care provider agency should assure that referral is for colposcopic evaluation and treatment. A DHHS computer-generated Pap Test Follow-up Form (DHHS 1011) will be sent to the health care provider agency for those patients needing follow-up. (See **Section III** "Instruction for Form Usage" on the DHHS 1011.)
- Treatment and follow-up is individualized, as directed by the QHCP.



Do Not Repeat Pap Test. Refer Patient.

7. Atypical Glandular Cells (AGC)

Glandular neoplasia is more difficult to diagnose than squamous neoplasia. Atypical glandular cells (endocervical or endometrial) may be described by the Pap report as any of the following:

- Atypical glandular cells
- Endocervical adenocarcinoma
- Endocervical adenocarcinoma in situ
- Endometrial adenocarcinoma
- Extrauterine adenocarcinoma
- Adenocarcinoma, NOS

Patient Notification and Education

Notify and counsel the patient regarding the seriousness of the Pap test report and the need for immediate medical care. Document your actions. Additional evaluation is necessary.

Clinical Management

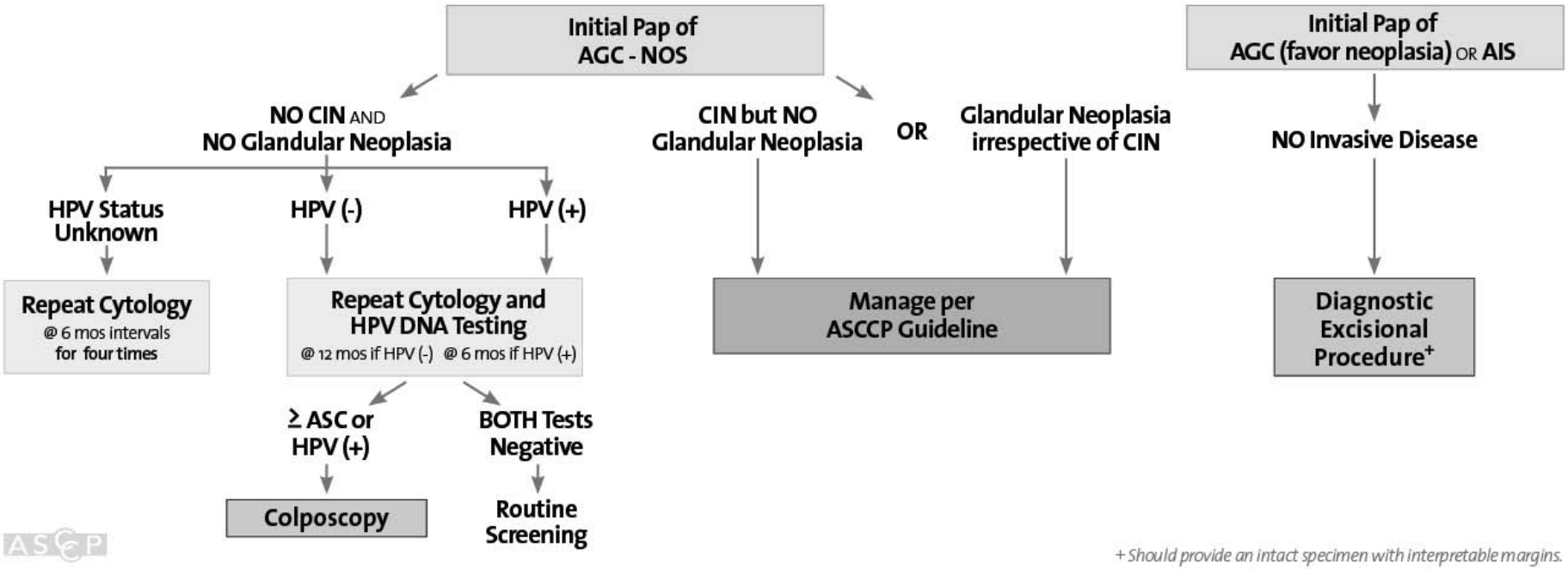
- Refer the patient to a Qualified Healthcare Provider (QHCP)[20] for medical follow-up for colposcopy and/or endometrial evaluation.
- Since patients with this Pap test finding all require colposcopy, the health care provider agency should assure that referral is for colposcopic evaluation and treatment. A DHHS computer-generated Pap Test Follow-up Form (DHHS 1011) will be sent to the health care provider agency for those patients needing follow-up. (See **Section III** "Instruction for Form Usage" on the DHHS 1011.)

Atypical Glandular Cells Algorithm – Refer to ASCCP Published Algorithms[18]

Initial Workup of Women with Atypical Glandular Cells (AGC)

^ If not already obtained. Test only for high-risk (oncogenic) types.
* Includes unexplained vaginal bleeding or conditions suggesting chronic anovulation.

Subsequent Management of Women with Atypical Glandular Cells (AGC)



+ Should provide an intact specimen with interpretable margins. Concomitant endocervical sampling is preferred.

8. Other Malignant Neoplasms

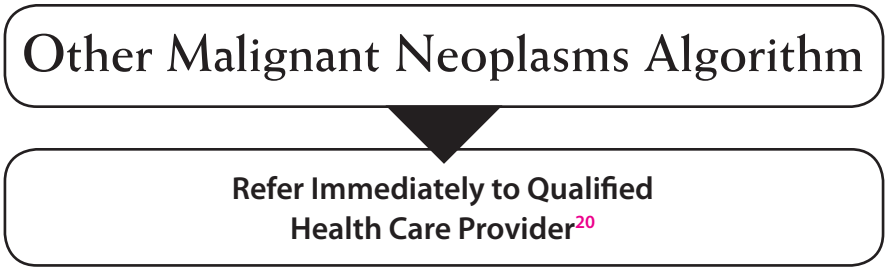
Cytologic evaluation sometimes discovers metastatic lesions such as ovarian, gastrointestinal, melanoma, etc. In these cases, the lab will report the findings as "other malignant neoplasms."

Patient Notification and Education

Notify and counsel the patient regarding the seriousness of the Pap test report and the need for immediate medical care. Document your actions. Additional evaluation is necessary.

Clinical Management

- IMMEDIATE referral must be made for medical follow-up to a QHCP[20].
- Since patients with this Pap test finding all require colposcopy, the health care provider agency should assure that referral is for colposcopic evaluation and treatment. A DHHS computer-generated Pap Test Follow-up Form (DHHS 1011) will be sent to the health care provider agency for those patients needing follow-up. (See **Section III** "Instruction for Form Usage" on the DHHS 1011.)
- Treatment and follow-up is individualized as directed by the QHCP.



Do Not Repeat Pap Test. Refer Patient.

C. Other Findings on Pap Test Reports and Definitions

1. **Reparative changes** – Changes seen when injured tissue attempts to re-establish its structure and function as it existed prior to injury. The injury can be due to causes such as radiotherapy, hysterectomy, cautery, biopsy, severe cervicitis, infection or inflammation. Repair is accompanied by varying degrees of inflammation.

2. **High estrogen level for age** – An increase in estrogen produces a cytologic pattern of maturation of squamous epithelium. Estrogen increase is especially evident in postmenopausal patients and women on hormone replacement therapy. Elevated estrogen effect is reported only on postmenopausal patients, based on the menstrual history and age as noted on DHHS Form 1010.

   NOTE: "High estrogen level for age" is a finding that is determined from a vaginal scrape sample ONLY. Women with a finding of "high estrogen level for age" who are not on hormone replacement therapy should be referred to QHCP[20].

3. **Hyperkeratosis (leukoplakia, white patches)** – Indicates that a large number of anucleated squamous cells are present in the Pap test. Hyperkeratosis is often diagnostic of benign leukoplakia or a reaction to a chronic irritation as seen in uterine prolapse, inflammation, or chemical or physical trauma to the cervical mucosa. On rare occasions, hyperkeratosis may overlie a significant lesion or dysplastic condition. Hyperkeratosis may exist alone or in combination with parakeratosis.

4. **Parakeratosis** – Parakeratosis is a protective surface reaction of the squamous epithelium. It is characterized by the formation of multiple layers of compact miniature squamous cells with pyknotic nuclei. Parakeratosis may overlie and mask a significant epithelial abnormality such as dysplasia.

5. **Focal reactive changes** – This finding is not clinically significant. No special follow-up is required and the woman should be screened at regular intervals.

6. **Benign-appearing endometrial cells present in a woman over 40** – If patient is premenopausal or post-hysterectomy, this is not clinically significant. If she is postmenopausal, refer to QHCP for further evaluation.[12]

7. **Sexually Transmitted Infections** – Consult recommendations of the *Sexually Transmitted Diseases: Assessment Prevention, and Treatment Protocols*, HIV/STD Prevention and Care Branch and current recommendations regarding sexually transmitted diseases from the *Centers for Disease Control and Prevention, Clinical Practice and Treatment Guidelines*.

II. Procedure for Obtaining a Pap Test

Procedure for Obtaining a Pap Test

A. Purpose

It is important to remember that a Pap test is a screening test, and as such it is intended to be used in an asymptomatic population. Symptoms that may be due to neoplasia should be completely evaluated. A Pap test in this situation is not appropriate management. In the presence of frank bleeding, the Pap test should not be obtained. If there is suspicion that the patient's bleeding may be due to a neoplastic process, the patient should be referred for prompt, complete evaluation. **When considering the order of collecting specimens:** The Pap smear should be performed first, before the bimanual exam and/or before any testing is undertaken for gonorrhea and/or chlamydia infection.[21] Collect gonorrhea, chlamydia and Pap specimens according to local protocol using review of patient symptoms and clinic requirements. **Please note:** Collecting any other test(s) sample(s) before collecting the Pap test may remove cells diagnostic for cancer and its precursor lesions and may cause false negative Pap test results.

B. Preparation of the Patient

At the time the appointment is made for an examination which includes a Pap test, the patient should be advised that the likelihood of getting a higher quality Pap test is increased by putting **nothing** in the vagina for 48 hours prior to the exam. This includes:

- No intercourse
- No tampons
- No douching
- No vaginal medications or lubricants
- No vaginal contraceptive

In addition to the above recommendations, if possible the patient should be tested as close to 2 weeks after the first day of her last menstrual period, and definitely not when she is menstruating.[21]

C. Equipment

A clinic room set up for a female pelvic exam, including the following:

- Good lighting (gooseneck lamp) must be available
- Specula
- Plastic spatula
- Endocervical brush (Do not use in pregnant women.)
- Vial of PreservCyt solution for *ThinPrep* Pap test
- Test tubes with normal saline (saline replaced every 30 days)
- Cotton applicators (large and small)

- N.C. State Laboratory of Public Health Pap Test Screening Form (DHHS Form 1010) or Reference Lab Forms
- Individual zip lock bag
- Mailing container for bagged *ThinPrep* vials or container from Reference Lab

D. Procedure for *ThinPrep* Testing

1. Vial of PreservCyt solution may be labeled **before** the test is taken. Print patient's last name and then first name on vial. Make sure name is legible. A computer generated name label may be used (preferred). Place computer printed or hand-written label **horizontally** around the vial so that uncovered portion of the vial remains uncovered and toward the top of the vial so the vial's expiration date remains viewable. This positioning will allow the depth of liquid in the vial to be viewed and allow a place for a bar code to be added sometime in the future.

Complete Pap test screening form (DHHS Form 1010). Follow instructions on back of form. **All requested information is vital**. It is essential that the patient's correct name, both last and first, is on BOTH the DHHS Form 1010 and the vial. Please indicate previous or maiden name in spaces provided below the Social Security number. The DHHS patient identification number (Social Security Number) **must** be on the form for correct identification. The **Medicaid Number**, if applicable, must be on the DHHS Form 1010 for billing purposes; therefore, **it is imperative** that Medicaid numbers are submitted to the laboratory. Certain elements for pap smears are required by federal CLIA 04 regulations such as the patient's last menstrual period, and documentation of whether the patient had a previous abnormal report, treatment, or biopsy. Other elements (e.g., IUD use, hysterectomy, BCP or Depo-Provera use, etc.) are important in the evaluation of any cellular changes.

2. Ensure that the patient has emptied her bladder. Give patient a gown with instructions for wearing. Assist patient onto the examining table.
3. Assist patient to lithotomy position, drape and adjust light.
4. Put on gloves. (Recommend double gloving.) Proceed at relaxed pace and explain each step of procedure to patient.
5. Insert the speculum
   a. Place one or two fingers just inside or at introitus.
   b. Press down on perineal body to relax muscles.
   c. Tell patient that speculum is about to be inserted and ask her to relax pelvic floor muscles.
   d. Gently insert closed speculum at 45-degree angle downward as you withdraw fingers.
   e. Hold bills at oblique angle and direct speculum toward posterior wall.
   f. With handle, rotate bills to horizontal position maintaining downward angle and pressure posteriorly.
   g. Insert speculum fully, and direct bills accordingly.

h. If unable to locate cervix, pull back on speculum slightly and redirect bills anteriorly; cervix will usually become visible.
i. Lock bills when cervix becomes visible.

6. Obtain the ThinPrep Pap Test Sample

Collect samples for the *ThinPrep* Pap test from **both ecto- and endocervix**.

a. To Collect the Sample from the Ectocervix
   (1) Select contoured end of plastic spatula and rotate 360° around entire ectocervix while maintaining tight contact with ectocervical surface. Remove spatula.
   (2) Rinse contoured end of plastic spatula in vial of PreservCyt (*ThinPrep*) Solution by swirling vigorously **ten (10)** times. Leave the spatula in the vial while collecting the endocervical sample. (Step 2.)

   It is **most** important that an adequate sample be taken from the squamocolumnar junction, also called the transformation zone. The location of the squamocolumnar junction can be identified by a change in color and texture between the squamous and columnar epithelia. The squamous epithelium appears as pale pink, shiny and smooth. The columnar epithelium appears reddish with a granular surface.
b. To collect a sample from the endocervix
   (1) Insert the cytobrush device into the endocervix only until the bottom-most bristles are exposed. Slowly rotate one-fourth to one-half turn in one direction. Remove brush. **Do not over-rotate. Additional rotation may cause bleeding and contaminate specimen.**
   (2) Rinse the cytobrush in the PreservCyt (*ThinPrep*) solution **ten (10)** times while pushing it against the wall of the vial. Swirl the brush vigorously to further release material. After swirling the brush in the vial ten times, use the spatula to push any remaining material from the brush. Discard the spatula and the brush.
c. To close the vial for shipping:
   Tighten the PreservCyt vial cap so that the **torque line** on the cap **meets** the **torque line** on the vial.
d. Make sure that the vial is properly labeled with the patient's name, **last name and first name**. Make sure the name on the **vial matches** the name on the **form**.

7. Special Considerations for Pap Test Collection:

- Do not use endocervical brush in pregnant women.
- Have endocervical brush and spatula in hand.
- If squamocolumnar junction **cannot** be identified: place elongated edge of spatula into cervical os, press firmly and rotate 360°, OR
- If squamocolumnar junction is identified on the ectocervix, obtain sample using the regular end of the spatula.
- For the patient who has had a hysterectomy, use regular tip of plastic spatula to scrape the area of the vaginal cuff. (Refer to page I-3 to determine if your patient who has had a hysterectomy should have a screening Pap test.)

- Lubricant jellies should not be used to lubricate the speculum.
- Remove excess mucus or other discharge present before taking sample. This should be gently removed with ring forceps holding a folded gauze pad.
- Remove inflammatory exudate from the cervical canal before taking the sample. Remove by placing a dry 2x2 piece of gauze over the cervix and peeling it away after it absorbs the exudate or by using a dry proctoswab or scopette.
- The cervix should not be cleaned by washing with saline or it may result in a relatively acellular specimen.
- The sample should be obtained before the application of acetic acid.

8. Packaging and Shipping of *ThinPrep* Pap Test Samples/Specimens

Refer to State Lab Web site (http://slph.state.nc.us) for detailed instructions.

a. Make sure that PreservCyt vial is labeled with patient's last and first names.
b. Make sure that DHHS Form 1010 (Pap Test Screening Form) is completed. Indicate any name changes from previous submissions in the spaces provided.
c. Place up to 15 PreservCyt vials (with enough absorbent material to absorb leaks) in a zip-lock plastic bag.
d. Place plastic bag(s) and form(s) in a heavy corrugated cardboard box. Place the forms in the box in a separate bag or envelope. If more than one bag of vials is included, label the bags and forms as bag 1, bag 2, etc. Boxes containing 51 vials or more must have a flammable label attached to the box. Attach a peach-color State Laboratory **Cytology Mailer Label** on the box and send to the State Laboratory via state courier mail service or U.S. Postal Service.

Procedure Notes

- Have readied a vial of PreservCyt (*ThinPrep*) Solution labeled with patient's name, last name and first name.
- Be sure Expiration Date on the PreservCyt is **current**. The State Laboratory **will not test samples when the expiration date has passed**. The sample/specimen will be returned to the health care provider agency. The State Laboratory **will not refund** health care provider agencies for expired vials.
- **Do not hold specimens in the lab for extended periods**. Ship specimens to the SLPH several times each week. FDA regulations require that the ThinPrep slide must be prepared within three weeks of collection.
- Improved patient preparation or clinician technique may correct the cause of the unsatisfactory or partially obscured Pap.[22]

E. Unsatisfactory Cytological Specimens

Unsatisfactory cytological specimens fall into two categories:

- Unsatisfactory: examined
- Unsatisfactory: rejected

1. The most common reasons for unsatisfactory: examined samples/specimens are:
   a. Insufficient number of cells
   b. Failure to properly rinse collection devices in vial of PreservCyt Solution
   c. Bloody specimens
   d. inflammation[22]
   e. presence of organisms[22]

2. The most common reasons for unsatisfactory: rejected specimens are:
   a. No name on vial
   b. Illegible handwriting or stamped name
   c. Name on vial does not match name on form
   d. Pap collected after expiration date of vial
   e. Two vials with same patient's name and two forms with two different names.
   f. slide breakage or leakage of liquid specimens[22]

3. The most common errors in usage of form are:
   a. No patient ID number/Social Security number
   b. Failure to indicate patient name change
   c. The patient history is incomplete
   d. There is no return address of provider
   e. No patient name on form
   f. Writing is illegible on form
   g. The patient's name on the vial and the form do not match
   h. Two vials are sent with one form

F. References

1. *Pap Test Manual: Guide for Local Health Care Departments*, NC DHHS, June 2004.

2. *Improving The Quality of Clinician Pap Smear Technique and Management, Client Pap Smear Education, and Evaluation of Pap Smear Laboratory Testing: Resource Guide for Title X Family Planning Projects*, U.S. Dept. of Health and Human Services, September 2003.

3. www.cdc.gov/clia/regs/subpart_k.aspx#493.1241

III. Cancer Screening Follow-up DHHS Form 1011

Cancer Screening Follow-Up DHHS Form 1011

Purpose

- To provide the State Laboratory of Public Health with diagnostic and tissue study data on Pap tests submitted to the Cancer Cytology Unit where abnormal cytological or clinical findings have been reported
- To comply with the Clinical Laboratory Improvement Amendments of 2004 (CLIA '04) regulations
- As an integral part of the Laboratory's Quality Assessment Program. Laboratory quality is dependent on biopsy correlation.

Cytology Laboratory Initiated Form

The DHHS 1011 (Cytology Screening Follow-up Form) accompanies the State Laboratory of Public Health Cancer Cytology Pap test report when the following cytological findings are present:

- AGC (atypical glandular cells)
- ASC-H (atypical squamous cells- cannot exclude HSIL)
- Second sequential ASC-US (atypical squamous cells- undetermined significance)
- LSIL (low grade squamous intraepithelial lesion)
- HSIL (Moderate and/or severe squamous intraepithelial lesion, CIS)
- AIS (adenocarcinoma in situ)
- Malignancy

Health Care Provider Agency Initiated Form

Under certain circumstances and for some patients who have abnormal cervical conditions detected on clinical exam, the health care provider agency initiates the DHHS 1011. To provide the DHHS essential follow-up data for cytological evaluation, please request a DHHS 1011 from the Cancer Cytology Unit (919-733-7146) when:

- Previous Pap test findings were negative; however, physical findings or surgery indicate a lesion.
- The clinician returns the Referral DHHS Form 2734 with abnormal tissue findings.
- Patient was referred for further follow-up because of clinical findings.
- Refer to Quality Assurance Recommendations (page IV-36) for other referral and follow-up guidance.

Instructions for completing the DHHS Form 1011

Tissue Studies Completed

- Retain the DHHS 1011 in the patient's chart until diagnostic tests are completed.
- Circle the methods and diagnosis when results are returned from the physician or attach a copy of the physician's report to the DHHS 1011 and return.
- A copy of the Referral Form 2734 may be attached when the tissue report is not available.

No Tissue Studies Planned

- Circle "No Tissue Studies Planned".
- Enter the date of the repeat Pap and name of examining cytology lab if one is obtained.

Important Note

A copy of a lost Form 1011 can be obtained by notifying the Cancer Cytology Laboratory at the address or telephone number below:

Cancer Cytology Laboratory
State Laboratory of Public Health
Post Office Box 28047
Raleigh, NC 27611-8047
Telephone (919) 733-7146

Tracking the Form 1011

The **Form 1011 Not Returned Report** is available on the State Lab's web site (http://slph.state.nc.us). This report:

- Lists all Forms 1011 generated by a specific county/clinic that have not been returned and entered into the laboratory information system;
- Monitors the return of these follow-up forms to the lab; and
- Provides assurance to the health care provider agencies that the patient is not lost for follow-up with a potentially life-threatening disease.

Importance of Returned DHHS Form 1011

- The information is entered into the State Lab data system (LIMS).
- The cytotechnologist and pathologist use this important diagnostic data when reporting all future Pap tests received on a patient.
- The slides are reviewed when negative biopsy results are received on an abnormal Pap or positive biopsy results on a negative Pap.
- CLIA '04 requires that all cytology labs collect correlation statistics on biopsy results versus HSIL Pap test reports and also monitor the percentage of HSIL Pap reports that have a returned tissue follow-up report.
- Many of the slides are used for continuing education purposes after biopsy correlation is confirmed. Patient confidentiality is maintained on all specimens used in continuing education studies.

Patient
Name:
I.D. #

N. C. Department of Health and Human Services
Division of Public Health

State Laboratory of Public Health
306 N. Wilmington St., PO Box 28047
Raleigh, North Carolina 27611-8047

CYTOLOGY SCREENING FOLLOW-UP

Current Pap Screening Report:

Name and Address of Screening Clinic:

Colposcopy and biopsy results are an integral part of the Cancer Cytology Quality Assessment Plan. Please return this form promptly upon completion of diagnostic testing. CLIA requires correlation of all HSIL (high grade intraepithelial lesions) with tissue studies so return of these is of utmost importance. The Cancer Cytology Unit maintains statistics on all abnormal Paps and would appreciate the return of all DHHS 1011 Forms.

Please circle the appropriate entities.

TISSUE STUDIES COMPLETED

DIAGNOSTIC METHOD:
1 – Colposcopy
2 – Directed Punch Biopsy
3 – Cone Biopsy
4 – ECC
5 – LEEP
9 – Other (specify)
10 – HPV

PATHOLOGICAL DIAGNOSIS:
1 – Benign
2 – Condylomata
3 – CIN I (mild dysplasia)
4 – CIN II (mod. dysplasia)
5 – CIN III (marked dysp./CIS)
6 – Squamous cell carcinoma
7 – Adenocarcinoma
9 – Undetermined

Site: _____

Stage:
1 – In Situ
2 – Locally Invasive
3 – Regional Nodes
4 – Remote Metastasis
9 – Unknown

Physician's Name: _____ Date:_____

NO TISSUE STUDIES PLANNED

Name of laboratory examining repeat Pap Test: _____

Date: _____ Results: _____

Instructions: Please complete this form when diagnostic testing is completed. A copy of the tissue report and colposcopy or LEEP may be attached in lieu of completing this form. Please circle NO TISSUE STUDIES PLANNED and return so that the case will not appear on the Follow-up 1011 Forms Not Returned report when the client is not scheduled for further diagnostic studies.

DHHS 1011 (Revised 7/04)
Laboratory (Review 7/05)

For additional copies or further information contact the Cancer Cytology Branch at (919) 733-7146

IV. Quality Assurance Recommendations

Quality Assurance Recommendations

A. Quality Assurance Recommendations for Cervical Cancer Screening

For a cervical cancer screening to be effective, health care providers need to have systems in place to ensure that any abnormalities detected by clinical pelvic exam or Pap test are appropriately followed up. Notify patients with abnormal test results promptly. Track patients who need additional diagnostic or treatment to assure they get proper follow-up care.

Five key steps are necessary for managing the results of cervical cancer screening:

1) Track Pap test and any diagnostic tests until results are obtained
2) Follow requirements for patient notification. At least three attempts must be made to locate and inform the patient of abnormal screening results. The last attempt must be by certified letter. Written documentation of all attempts must be included in the medical record.
3) Document that notification has occurred
4) Refer patients with any abnormalities on clinical pelvic exam or Pap test for appropriate follow up
5) Track referrals to make sure that patients have actually received follow-up

Each clinic might have a different mechanism for ensuring that all of these steps have occurred, but all clinics should all have written guidelines, standards, and policies for management of cervical cancer screening. Written policies must be accessible to staff. This manual contains recommendations that should be considered in the development of local policies. Agencies providing Pap screening by RNs must have policies and procedures in place for assuring competency and documentation of competency for each nurse performing clinical exams. Policies should be reviewed at least annually and revised as needed.

The following elements are integral to a good follow up system.

1. **Designation of a responsible person:** The person designated as having responsibility for follow-up of cervical cancer screening should be a nurse who has knowledge of cervical cancer screening programs and familiarity with guidelines regarding follow-up of patients with abnormal Pap test results.

2. **A referral plan:** The referral plan will contain written procedures for referring patients with abnormal findings, including referral resources, the process of referring, and the preparation of eligibility forms, if applicable. All education and counseling protocols should be included, along with a list of educational materials used to assist the patient in understanding the abnormal test result or any additional diagnostic tests that may be done.

3. **A follow up-plan:** The follow up plan will contain written procedures that ensure the patient was referred to a provider, needed services were provided, and results of the referral returned to the agency. For those agencies sending Pap tests to the State

Laboratory for Public Health, include instructions on completing and submitting the DHHS 1011 form in the follow up plan.

4. **A tracking system:** Clinical management of patient is improved with a tracking system. Tickler files, computerized databases or handwritten logs are common methods of tracking patients. The system alerts staff of patients' status, especially abnormal cervical screening, and provides a simple tool for follow-up. Any tracking system must be checked at predetermined intervals to ensure follow-up is completed. The following is a suggested general process for cervical screening tracking:
   - All pap tests ordered are logged into a tracking system.
   - When results are received by the agency, the person responsible for follow-up reviews the reports.
   - Results requiring no intervention require patient notification. The report is initialed and filed in the medical record.
   - Results requiring follow-up are reviewed, the patient is notified, and the plan of care is determined based on this manual, local policy, and consultation with the medical advisor.
   - The plan of care and notification of the patient are documented in the medical record.
   - The nurse responsible for patient follow-up enters information in the tracking system and monitors the progress of the patient until follow up is complete

Tracking Systems Remind the Staff to:

- Document all patient contacts
- See test and examinations ordered and compare to tests with no results
- Review patients with incomplete interval follow-up (monthly, quarterly, etc.)
- Develop procedures to overcome patient-related barriers to follow-up, for example, telephone reminders, mailing reminders
- Attempt to contact patients three times to assure that patients are receiving treatment
- Use Certified Mail on the third attempt to notify patients

5. **Internal quality assurance:** Periodically (at least annually), chart audits should be performed to track the percent of women with abnormal results who receive definitive diagnostic and therapeutic procedures. Documentation of findings and corrective action must be on file.

B. Pap Screening Services Evaluation Checklist

Methodology

What is the Pap method being provided?

- ❑ *ThinPrep*
- ❑ *SurePath*
- ❑ Conventional

What are the dysplasia and ASC-US rates for each method used and the lab's overall rates?

What is the reporting format used?

- ❑ Bethesda 01
- ❑ Bethesda
- ❑ Other (specify) _____

Cost

What is the current cost per test?

How long is the current price guaranteed?

How often does the price of testing increase?

Are billing invoices clear and correct?

Service

What is the turnaround time?

Is consultation available for reporting and follow-up guidelines? ❑ Yes ❑ No

Are statistical reports provided with the number of tests submitted, breakdown of results in each reporting and specimen adequacy category, and a report of follow-up of abnormal results? ❑ Yes ❑ No

Is it easy to contact lab personnel and get answers or resolutions to problems?
❑ Yes ❑ No

Can status of a specimen be checked or a report downloaded from the Internet?
❑ Yes ❑ No

Quality

What is the correlation rate of biopsy to Pap report?

How many slides are cytotechs required to read per day?

How many cytotechs are employed? Are all cytotechs ASCP certified? Average years of experience of cytotech staff?

What is the frequency of staff turnover?

What is the average slide per day per cytotech?

Are all slides screened during regular working hours? Is overtime mandatory for cytotechs? What percentage of work is screened after hours?

Is all work done at one site?

What percentage of negative slides is rescreened? Are the cytotechs responsible for performing this rescreening in addition to the daily requirement of first screens?

What Proficiency Testing Program is used and what has the performance history been for the lab and individual cytotechs?

What type of competency assessment is done for cytotechs?

Ask for a copy of the Cytology Laboratory Quality Assessment Plan.

Is an automated screening device used for screening? ❑ Yes ❑ No
If yes, does a cytotech still review every slide? ❑ Yes ❑ No

Ask for an organizational chart showing chain of command and certification of each level.

Is an ASCCP certified cytotechnologist in charge of the cytoprep area?
❑ Yes ❑ No
How many years of experience does this person have?
Must these duties be performed in addition to screening slides? ❑ Yes ❑ No
If so, how many slides per day does this person average?

Are any off-label procedures being used in the processing of gynecologic slides?
❑ Yes ❑ No

How many staff pathologists review Pap slides? What percentage of slides received does a pathologist review?

Is there any pending litigation concerning Pap reporting? ❑ Yes ❑ No

Has the lab been involved in prior litigation of any kind related to Pap screening services? ❑ Yes ❑ No

Ask for certificates of accreditation (CAP, CLIA, JCAH, etc.) and accreditation inspection reports.

References

Ask for customer references.

Using the questions listed above as a guide, are customers satisfied with:

- ❑ Methodology?
- ❑ Service?
- ❑ Cost?
- ❑ Quality?

V. Appendices

Appendix A

State Laboratory Bethesda Reporting System

Cancer Cytology Unit
Bethesda 2001 Pap Test Reporting Categories and Descriptions of Cellular Changes

Specimen Adequacy:

SATISFACTORY FOR EVALUATION: (describe presence or absence of endocervical/ transformation zone and any other qualifying indicators)

UNSATISFACTORY:

Specimen Examined: (inadequate cellular component or other quality statement)
Specimen Rejected: (specimen unlabeled, name on vial and form do not match, etc.)

Cytologic Findings Suggest:

Negative For Intraepithelial Lesion Or Malignancy

(Reparative, inflammatory and reactive changes will be indicated under this heading.)

ORGANISMS:

Organisms morphologically consistent with *Trichomonas Vaginalis*
Fungal organisms morphologically consistent with *Candida species*
Cellular changes associated with *Herpes Simplex Virus*
Bacteria morphologically consistent with *Actinomyces*

Other Findings:

Endometrial cells in a patient over the age of 40.

Epithelial Cell Abnormalities

Squamous

- ASC-US: atypical squamous cells- undetermined significance
- ASC-H: atypical squamous cells- favor high grade squamous intraepithelial lesion
- LSIL: low grade intraepithelial lesion encompassing mild dysplasia and HPV
- HSIL: high grade intraepithelial lesion encompassing CIS, moderate and severe dysplasia
- Squamous Cell Carcinoma

Glandular

Atypical:

Endocervical cells
Endometrial cells
Glandular cells

Atypical:

Endocervical cells, favor neoplasia
Glandular cells, favor neoplasia

Endocervical Adenocarcinoma in Situ

Adenocarcinoma:

Endocervical
Endometrial
Extrauterine
Not otherwise specified (NOS)

Other Malignant Neoplasms: (specify)

Educational notes and comments:

Suggest short-term vaginal estrogen therapy and repeat
Suggest treatment of inflammation and repeat
Please obtain specimen at mid-cycle for optimal results
Hyperkeratosis may mask a more serious condition
Suggest treatment of inflammation and colposcopy
Glandular cells, cytologically benign, in a post hysterectomy patient
Suggest colposcopy/biopsy/ECC if clinically appropriate

Reflex High-Risk HPV DNA Testing

The HPV Test

Following the 2006 Consensus Guidelines published in October 2007 (**www.asccp.org/consensus/cytological.shtml**), NCSLPH will test patients greater than 20 years of age with ASC-US (Atypical Squamous Cells of Undetermined Significance) Pap result for the presence of high risk HPV genotypes using the Digene Hybrid Capture 2 High-Risk HPV DNA test. This assay detects several of the high risk genotypes (HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68), but does not distinguish among them. The reports simply will indicate that high risk genotypes either were detected or were not detected in the patient's sample.

The Process

NCSLPH receives *ThinPrep*® vials from local health departments and processes them daily. Cytotechnologists review all prepared slides and record their results following a tightly controlled quality assurance process. NCSLPH sends all slides with abnormal results to a pathology group for final review and approval. After the ASC-US result is confirmed by the pathologist, the remaining patient sample in the *ThinPrep*® vial will be transferred from Cancer Cytology to Virology/Serology-Bacterial STD for subsequent HPV testing. The final laboratory report will include both pathology and HPV results on the Cancer Cytology form.

Turnaround Time (TAT)

NCSLPH will perform HPV testing twice a week in order to maximize efficiency when performing this lengthy procedure. Because HPV testing will only be performed after the final pathology report is received, the effect on TAT is expected to be a delay of no more than two to three days than is currently observed for abnormal reports.

Unsatisfactory Samples

Apart from the routine reasons a sample is deemed unsatisfactory for testing (questionable patient or sample identification, missing test requisition, overtly bloody sample), there may be reasons a sample is unsatisfactory for HPV testing, such as having insufficient quantities of remaining *ThinPrep*® sample required to perform the reflex test. If NCSLPH is unable to perform the test for this reason, a comment will be included in the report.

Our goal is to consistently produce high quality, accurate and timely tests results. In the case of HPV testing, providing information to health care providers about the presence or absence of high risk genotypes allows for better patient management when following up ASC-US test results.

HPV DNA Testing

HPV high risk: negative
HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68 not detected
Low likelihood of underlying CIN 2-3 or cancer
Results are not intended to prevent women from proceeding to colposcopy

HPV high risk: positive
HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68 detected
Low but increased likelihood that underlying high grade CIN will be detected at colposcopy

HPV high risk: unsatisfactory
QNS-Quantity of specimen left in *ThinPrep*® vial not sufficient for HPV testing

If you have any technical questions about the HPV test, please call Virology/Serology at 919-733-7544 and ask for Myra Brinson or Mary Noel Dodd. For any technical questions about Pap testing, please call Cancer Cytology at 919-733-7146.

Source: Memo from Dr. Leslie A. Wolf, North Carolina State Laboratory of Public Health Director, dated January 10, 2008.

Appendix B

Critical Value Notification

Critical Value Pap Reports

CLIA requires notification to a nurse of all Pap reports containing critical values. This alerts the submitter that a critical value report has been mailed and that its receipt should be tracked to avoid a lost critical value report. The lab must have confirmation that the critical value report was received by the submitter when the notice is left on voice mail. Since HIPAA regulations prevent leaving patient identifiers on voice mail, the nurse must call the lab to verify receipt of the message and to get the patient's name and the cytodiagnosis.

The lab should be notified if the report is not received within a few days or the report may be downloaded from the State Lab web site (**http://state.nc.us**) immediately.
The State Lab issues Critical Value notification for the following Pap reports:

- High-grade intraepithelial lesions (HSIL)
- Cancer
- Herpes in pregnancy
- Amended reports

In an effort to provide more timely notification of critical values and amended reports, the Cancer Cytology Unit at the N.C. State Laboratory of Public Health is formatting an e-mail list of nurse supervisors in the local health departments. The email notice of a Critical Value report will contain only the lab accession number to ensure HIPAA compliance. The report and additional patient information may be accessed from the N.C. State Laboratory web site (**http://slph.state.nc.us**) or by contacting the Cancer Cytology Unit at 919-733-7146. An e-mail return receipt will document the confirmation of the critical value notice.

On the following survey, please list the name, phone number and e-mail address of the nurse supervisor and another contact that would be responsible for forwarding the Pap report information to the appropriate clinic supervisor so that receipt of the report is tracked.

Please complete the attached survey and fax to:

Cancer Cytology Unit
Clerical Supervisor
919-715-0171

If you have any questions, please contact the Cancer Cytology Unit at 919-733-7146. Thank you for taking the time to complete this survey and working with us to improve the timeliness of your reports.

Survey for Pap Report Notification 2008

Facility: _____

Address: _____

_____

_____

Primary Contact:

Nurse Supervisor: _____

E-Mail Address: _____

Phone Number: _____

Additional Contact:

Name: _____

E-Mail Address: _____

Phone Number: _____

Appendix C

Cervical Cancer Screening Policies

North Carolina Breast & Cervical Cancer Control Program (NC BCCCP)

Cervical Cancer Screening Policy

Effective January 2008

Introduction:

In 2005, 138 North Carolina women died of preventable cervical cancer.[1] The primary focus of cervical cancer screening is to identify and treat pre-cancerous cervical lesions and detect and treat cervical cancer at an early stage. The incidence of cervical cancer has decreased significantly in the years since World War II, in large part because of early detection efforts using the Pap test. When cervical cancer is detected early, the likelihood of survival is almost 100 percent with timely and appropriate diagnostic follow-up and treatment.

In early 2005, CDC convened a panel of cervical cancer experts in order to examine and weigh the scientific and programmatic evidence related to cervical cancer screening practices in the NBCCEDP. The panel recommended reimbursing for liquid-based cervical cytology (LBC) on a biennial basis for the following reasons:

- Patients accept the LBC because their experience is essentially identical to that of a conventional Pap test.
- Simplicity of "reflex" testing: Women whose cervical cytology shows ASC-US benefit from HPV DNA testing to guide the diagnostic process. This practice is known as reflex testing. Those providers who collected the original cytological specimen in a liquid medium can take a sample of that liquid to be tested for HPV DNA - i.e., the patient need not return to the clinic for another office visit for the collection of another specimen.
- Market penetration: An estimated 80% of providers use LBC for cervical cancer screening. Disallowing reimbursement of this procedure presents a significant barrier to access for women in the program.
- Cost: Although the per-test cost of LBC is greater than for conventional Pap testing, and it generates slightly increased downstream costs due to a high rate of false positive results, an overall saving is expected be realized as a result of the extension of screening interval to two years.

The new policy supports the findings of the studies that strongly recommend that:

(1) Programs may reimburse for liquid-based cervical cytology (such as *ThinPrep* and *SurePath*) for primary cervical cancer screening at no more than the maximum allowable Medicare rate.

(2) The screening interval when using liquid-based tests is every two years. Programs must develop a means of ensuring that reimbursement for the liquid-based test it not provided more frequently than every two years.

(3) As with conventional Pap tests, when a woman has had three consecutive, normal cervical cancer screening tests documented within a 60-month period, the screening interval shall increase to once every three years. If a woman receives an abnormal

screening test result at any time, policies for follow-up of abnormal Pap tests and reimbursement of diagnostic procedures should be followed. Consistent with these recommendations, the cervical cancer screening policies for the NC BCCCP, effective January 2008, are as follows:

Eligible Women:

- Women between the ages of 18 and 64 years of age, with an intact cervix, are eligible to enroll in the NC BCCCP, provided their family income is at or below 250% of the current federal poverty level. Women between the ages of 40 and 64 may be screened using federal BCCCP dollars. Women between the ages of 18 and 39 may be screened using state BCCCP dollars.
- Women covered by Medicare-Part B and/or Medicaid are not eligible to enroll in the NC BCCCP. Women who are enrolled in and receiving services under Title X (Family Planning) are not eligible to have Pap tests reimbursed using NC BCCCP funds.
- Women between the ages of 18 and 39 are eligible to enroll in the NC BCCCP for diagnostic work-up of abnormal Pap results, provided their family income is at or below 250% of the current federal poverty level. Federal BCCCP dollars may be used to pay for the diagnostic workup.

NC BCCCP Cervical Screening Services Priorities:

- **Increase screening for eligible women never or rarely screened. Never or rarely screened is defined as women having no previous Pap test or who have not had a Pap test within five years.**
  - At least 20% of all NC BCCCP women newly enrolled for cervical cancer screening should meet the definition of never or rarely screened (Women who have not had a Pap test in the last 5 years).

    The screening interval when using liquid-based test is every two years. Programs must develop a means of ensuring that reimbursement for the liquid-based test is not provided more frequently than every two years.
- **Decrease over-screening among women enrolled in the NC BCCCP.**
  - At least 75% of NC BCCCP women with three consecutive normal Pap tests within a five-year (60 months) period, as documented in the NC BCCCP data, will not receive a fourth biennial Pap test, and are transitioned to Pap testing performed only every three years.
  - Prior to obtaining these three consecutive Pap tests with normal results (Bethesda category 1) within a 60-month period, NC BCCCP funds may be used to reimburse for screening Pap tests of eligible women on an every-other-year biennial basis.
  - If a woman receives an abnormal screening result at any time in these cycles, current NC BCCCP policies and protocols related to the follow-up of abnormal Pap tests and reimbursement of covered diagnostic procedures are to be followed.

- Once a woman has completed the recommended follow-up, she may again receive biennial Pap tests until three consecutive Pap tests within a five-year period are normal and documented in the NC BCCCP data.
- High-risk women, as defined in the "Pap Screening Manual: A Guide for Health Departments and Providers" or those designated by a physician as needing more frequent Pap tests, should have documentation in the medical record supporting more frequent Pap testing.
- NC BCCCP funds cannot be used to pay for cervical cancer screening in women who have had hysterectomies unless the hysterectomy was done for cervical cancer. However, women who have had a supracervical hysterectomy are eligible for cervical cancer screening under the NC BCCCP.
- An initial pelvic exam may be paid for with NC BCCCP funds to determine if a woman has a cervix.
- An annual pelvic/rectal exam may be performed but NC BCCCP funds may not be used to pay for or perform the exam.
- NC BCCCP funds may not be used to pay for follow-up pelvic exams in the absence of a Pap test, colposcopy or biopsy.
- NC BCCCP funds may not be used to pay for any cervical diagnostic or treatment services not included on the NC BCCCP services fee schedule (e.g., LEEP, conization, etc.).
- NC BCCCP funds may not be used to reimburse for a repeat Pap test which is performed simultaneously with colposcopy or colposcopy with biopsy, unless more than four months have passed since the initial Pap test was performed.

Reimbursement for Newer Diagnostic Procedures:

- NC BCCCP funds may be used to reimburse for liquid-based Pap test procedures for eligible women. The allowable rate is shown in the NC BCCCP Fee Schedule that is distributed annually to each screening contractor.
- NC BCCCP funds may be used to reimburse for high-risk Human Papilloma Virus (HPV) DNA tests on eligible women.

Appendix D

Procedure for Referral, Evaluation, Treatment (Colposcopy Providers)

List of Qualified Healthcare Providers (QHCP)

Procedure for Referring Patients Referral/Eligibility Requirements

Definitions

- Qualified Healthcare Providers (QHCPs)[20] provide outpatient services for the evaluation of an abnormal Pap test via colposcopy, and for the treatment of local cervical lesions via cryosurgery, laser conization, electrocautery or LEEP, or cold knife conization (CKC). They may also provide outpatient services for evaluation and treatment of non-cervical gynecologic dysplasia (vaginal and vulvar lesions) identified by physical examination, cytology, or biopsy.
- The Cancer Assistance Unit (formerly the Cancer Control Program) is part of the Chronic Disease and Injury Section of the Division of Public Health. The Cancer Assistance Unit assists patients who have little or no third-party reimbursement (i.e., medical insurance and/or Medicaid) and who meet residential, financial, and medical eligibility guidelines. See Appendix F for additional information.

A. Procedure

1. Health care provider (i.e., local health care provider agency) referral to a QHCP
   a. Referral is made to the QHCP for those patients with a Pap test result that is:
      (1) Second consecutive Pap test reported as Atypical Squamous Cells of Undetermined Significance (ASC-US); or
      (2) Single Pap test reported as Atypical Squamous Cells of Undetermined Significance (ASC-US) and a positive test for high-risk HPV DNA; or
      (3) Single Pap test reported as Atypical Squamous Cells: Cannot Exclude High-grade Squamous Intraepithelial Lesion (ASC-H); or
      (4) Single Pap test reported as Atypical Glandular Cells (AGC); or
      (5) Single Pap test reported as Low-grade Squamous Intraepithelial Lesion (LSIL); or
      (6) Single Pap test reported as High-grade Squamous Intraepithelial Lesion (HSIL) or Carcinoma.
   b. Referral is made to the QHCP for those patients with lesions of the vagina or vulva identified during physical exam that are suspicious for dysplasia or malignancy.
   c. Each patient has the right to choose to be referred to a QHCP who can provide a colposcopic examination.
   d. Each patient served by a QHCP is expected to pay for services through medical insurance, Medicaid, N.C. Cancer Assistance Unit, or self-pay. Limited diagnostic services for eligible patients may be paid by North Carolina's Breast and Cervical Cancer Control Program (NCBCCCP).

e. Referrals are made by the health care provider via telephone to the QHCP near the patient's residence or of the patient's choice.

2. Track and document the outcome of your referral.
3. Once you obtain results, complete the "Cancer Screening Follow-up Report" (DHHS Form 1011).

B. Publications

The following publications are available to assist the local health care provider agency:

1. **Purchase of Medical Care Services Payment Programs Manual.** This manual includes instructions for all payment programs in the DHHS. At least one copy of this manual has been sent to all local health departments. Additional copies of this manual may be requested from the Office of Purchase of Medical Care Services, NC DHHS, 1904 Mail Service Center, Raleigh, NC 27699-1904 **Telephone (919) 855-3672. Information is also available on the Internet at www.ncdhhs.gov/control/pomcs/pomcs.htm.**
2. **Cancer Assistance Unit (formerly the Cancer Control Program) Fee-For-Service Information Manual.** Copies may be requested from the Cancer Assistance Unit, NC DHHS, 1922 Mail Service Center, Raleigh, NC 27699-1922; **Telephone (919) 707-5321. Information is also available on the Internet at www.nccancer.org; or Telephone Patient Line: 1-866-693-2656.**

C. Patient Education

The patient should be given instructions along with counseling when the appointment is made for the QHCP. The following points should be stressed prior to appointment:

1. Do not douche, use intravaginal medications or tampons, lubricants, have intercourse, or use vaginal contraceptives for at least 48 hours prior to appointment.
2. When scheduling the appointment, suggest that the patient select a day not likely to be during her menstrual period.
3. Determine if patient has transportation needs and assist in facilitating transportation if necessary.

Partial List of Qualified Health Care Providers

Provider	Sub-Contractor	Phone	Other
Anson Co HD	Pinehurst Women's Clinic- Dr. J. Puleo 70 Memorial Dr., Pinehurst, NC	910-295-4342	
Beaufort Co HD	Washington Women's Care 1204 Brown St., Washington, NC	252-946-6455	
	Obstetrics and Gynecology of Washington 1210 Brown St., Washington, NC	252-946-6544	
Albemarle Health Serv.	Carolina Surgical Associates		
Carteret Co. HD	Carteret Surgical Assoc. PA 3714 Guardian Ave., Morehead City, NC	252-247-2101	
	Darryl C. Falls, MD 1508 Arendale St., Morehead, City, NC	252-726-7374	
	Carteret OB/GYN Assoc. 3511 John Platt Dr., Morehead City, NC	252-247-4297	
	Carteret Women's Health Ctr. 302 Penny Ln., Morehead City, NC	252-726-8016	
	Way Surgical Associates, PA 210 Penny Ln. Morehead City, NC	252-247-4769	
Craven Co HD	Eastern Carolina Women's Center 801 McCarthy Blvd, New Bern, NC	252-633-3942	
	Leo Jenkins Cancer Center 600 Moye Blvd, Greenville, NC	252-744-1888	
Goshen Medical Center	Duplin General Hospital 401 N. Main St., Kenansville, NC	910-296-0941	
	Sampson Regional Medical Center 606 Beaman St., Clinton, NC	910-592-8511	
	Wayne Memorial Hospital 2700 Wayne Memorial Drive, Goldsboro	910-736-1110	

Granville-Vance District	Center for Women's Health	
	Premier Women's Health Professionals	
Hertford County Public Health Authority	Women's Care of Ahoskie 606 S Academy St., Ahoskie, NC	252-209-3614
	Roanoke Chowan Women's Center 214 E. Church St., Ahoskie, NC	252-332-6111
Lincoln County HD	Lincoln Center for Women's Health* 1460 E. Gaston St., Lincolnton, NC	704-735-2134
	Lincoln OB-GYN* 275 Highway 16 N, Denver, NC	704-732-3346
Mecklenburg County HD	Carolinas Medical Center Myers Park & Health Department	
MTW District	Leo Jenkins Cancer Center 600 Moye Blvd, Greenville, NC	252-744-1888
	Tarheel Surgical 310 S McCaskey Rd., Williamston, NC	252-799-3006
Northampton	Women's Health Specialties	
	Halifax Pathology	
	Smith Church OB/GYN 244 Smith Church Rd., Roanoke Rapids	252-535-4343
Rural Health Group	Women's Health Specialist	
Stanly County HD	Carolinas Women's Health Center 929 N. 2nd St # 201, Albemarle, NC	704-985-1799

All are providing clinical services under BCCCP guidelines.

Appendix E

References and Resources

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[3] United States Cancer Statistics 2004 Incidence and Mortality, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Cancer Institute 2007.

[4] U.S. Preventive Services Task Force. *Guide to Clinical Preventive Services* 2007 Recommendations of the U.S. Preventive Services Task Force. Washington, DC: Agency for Healthcare Research and Quality, September 2007: 26-31.

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[11] ACOG. Healthy Women 2008. New evidence-based screening guidelines for pap tests (See also: **www.acog.org/acog_districts/dist_notice.cfm?recno=1&bulletin=2496**)

[12] Wright Jr.,Thomas C., MD; L. Stewart Massad, MD; Charles J. Dunton, MD; Mark Spitzer, MD; Edward J. Wilkinson, MD; Diane Solomon, MD "2006 consensus guidelines for the management of women with abnormal cervical cancer screening tests". American Journal of Obstetrics & Gynecology 197 (October 2007): 349-351.

[13] *National Breast and Cervical Cancer Early Detection Guidance Manual*, April 2007

[14] American College of Obstetrics and Gynecology, American Cancer Society. *Cancer Facts & Figures 2008*. U.S. Preventive Services Task Force: "Never or rarely screened" is defined as not having had a Pap test in the last five years.

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[18] Available at **www.asccp.org/pdfs/consensus/algorithms_cyto_07.pdf**

[19] North Carolina Breast and Cervical Cancer Control Program (NCBCCCP) Policy requires referral for treatment within 60 days.

[20] Qualified Health Care Provider (QHCP). For a partial list see Appendix D

[21] Cytyc Corporation Training Bulletin, 2005. part No. 86667-001 Rev. A

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Additional Resources

Agency for Healthcare Research and Quality (**www.ahrq.gov**)

American Cancer Society (**www.cancer.org**)

American College of Obstetricians and Gynecologists (**www.acog.org**)

American Society for Colposcopy and Cervical Pathology (ASCCP) (**www.asccp.org**)

Behavioral Risk Factor Surveillance System (BRFSS) (**www.cdc.gov/brfss**)

Centers for Disease Control and Prevention (**www.cdc.gov**)

Healthy People 2010 (www.healthypeople.gov) or (**http://wonder.cdc.gov/data2010**)

Jacobs Institute of Women's Health, States Profiles on Women's Health (**www.JIWH.org**)

Morbidity and Mortality Weekly Report (MMWR) (**www.cdc.gov/mmwr**)

National Cancer Institute (**www.cancer.gov**)

National Center for Health Statistics (NCHS) (**www.cdc.gov/nchs**)

National Women's Health Information Center (**www.4woman.org**)

N.C. State Center for Health Statistics (**www.schs.state.nc.us/SCHS**)

Seer Cancer Surveillance (**http://seer.cancer.gov**)

Tracking Healthy People 2010 (**www.cdc.gov/nchs/hphome.htm**)

U.S. Bureau of the Census (**http://census.gov**)

National Breast and Cervical Cancer Early Detection Program (NBCCEDP) (**http://cdc.gov/cancer/nbccedp**)

Appendix F

Breast and Cervical Cancer Medicaid (BCCM)

History of Breast and Cervical Cancer Medicaid (BCCM)

October 2000	Breast and Cervical Cancer Prevention and Treatment Act (106-354) enacted for eligible National Breast and Cervical Cancer Early Detection Program (NBCCEDP) patients.
January 2002	Eligible Clients of NCBCCCP begin to receive Breast and Cervical Cancer Medicaid for surgical intervention and other treatment of diagnosed breast and cervical cancers.

Do you have patients or do you know women who are eligible for and would benefit from Medicaid paying for their breast and cervical cancer treatment?

Patients must be referred to the local NCBCCCP prior to diagnosis to be eligible for Breast and Cervical Cancer Medicaid.

Be an advocate for women to receive needed intervention for breast and cervical cancers!

Women must be eligible for NCBCCCP . . .

Eligibility includes –

- Women who are at or below 250% of the Federal Poverty Guidelines, are uninsured or under insured, and are not covered by Medicare Part B.
- Preference is given to women ages 50-64 and ethnic minorities due to the greater incidence and/or mortality from these cancers.

Physicians Beware: A patient referred by a non-BCCCP provider must be referred and enrolled in BCCCP prior to receiving a diagnosis of breast or cervical cancer to be eligible for BCCM.

Enroll an eligible patient in NCBCCCP by . . .

- Referral to local NCBCCCP when there is an abnormal screening or diagnostic test result, but *before* cancer is diagnosed.
- Provide preliminary screening test (CBE, screening and/or diagnostic mammogram, Pap test, colposcopy, etc.) with referral.

Final diagnostic testing will be done through NCBCCCP with NCBCCCP funds.

Diagnosis made to eligible women through NCBCCCP opens the door to Medicaid eligibility. Application for BCCM is made through the local NCBCCCP provider.

For more information, contact the North Carolina Breast and Cervical Cancer Program 919-707-5300

Rev. 01/08

NORTH CAROLINA
Cancer Assistance Unit

we're here for you!

What is Cancer Assistance?

The ***Cancer Assistance Unit*** (CAU), formerly the Cancer Control Program, is a part of the North Carolina Comprehensive Cancer Program. The Cancer Assistance Unit provides information on cancer-related resources, services, and financial assistance for men and women with all types of cancers.

What type of financial assistance is available?

Cancer Assistance funds can cover medical care for eligible persons who need services for cancer diagnosis or cancer treatment.

- It can pay for inpatient, outpatient, or office/clinic services.

How do I qualify?

To qualify for ***Cancer Assistance*** you must meet the following requirements:

1. **Residency**
   - U.S. citizen and a permanent resident of North Carolina, or a migrant farm worker or the dependent of one.
   - INS documentation is required if you have applied for US citizenship or a permanent resident visa.

2. **Financial**

Income is based 115% of the federal poverty level. *(See Current Eligibility Income Scales on reverse side)*

3. **Medical**
   - Have symptoms or conditions that indicate cancer or be diagnosed as having cancer.
   - Not eligible for Medicaid and have little or no health insurance.
   - Have an estimated 25% or better chance of 5-year survival at the time of treatment.

What does Cancer Assistance pay for?

- Diagnostic services for up to 8 days for each fiscal year (July 1 to June 30).
- Treatment services for up to 30 days for each fiscal year (July 1 to June 30).
- Coverage usually includes doctor services in both inpatient (hospital) and outpatient as well as clinic or office visits.
- Payment is paid directly to the medical care provider or health care facility.

What is not covered?

Cancer Assistance does not cover:

- Drugs or medicines used outside the treatment facility
- Cost of travel mileage to and from diagnosis or treatment appointments

At the North Carolina Comprehensive Cancer Program, your health matters to us.

NORTH CAROLINA Comprehensive Cancer Program ...to ease the burden of cancer

North Carolina Cancer Assistance Unit

Financial Eligibility Income Scales

(Based on 115% of the federal poverty scale)

Family Size	1 July 2007 - 30 June 2008 Family GROSS Income	1 July 2008 - 30 June 2009 Family GROSS Income
1	$11,741	$11,960
2	$15,743	$16,100
3	$19,745	$20,240
4	$23,747	$24,380
5	$27,749	$28,520
6	$31,751	$32,660
7	$35,753	$36,800
8	$39,755	$40,940
	Add $4,002 for each additional person	Add $4,140 for each additional person

Sources for More Information

North Carolina Comprehensive Cancer Program, Cancer Assistance Unit
Division of Public Health
1922 Mail Service Center
Raleigh, North Carolina 27699-1922
Phone: (919) 707-5321
Fax: (919) 870- 4812
Patient Line (Toll Free): 1-866-693-2656
www.nccancer.org
(Questions, medical eligibility, program manual)

Purchase of Medical Care Services
1904 Mail Service Center
Raleigh, North Carolina 27699-1904
Phone: (919) 855-3701 (Eligibility)
(919) 855-3672 (To order forms)
Fax: (919) 715-3848

American Cancer Society
1-800-227-2345 (24-hour line)
Cancer Information Line
www.cancer.org

Cancer Information Service
National Cancer Institute
1-800-4-CANCER
(1-800-422-6237)
www.cancer.gov
(To learn more about cancer)

CARE-LINE
Information and Referral Service
(English/Espanol)
1-800-662-7030 (919) 855-4400
Provides information and referral on human services provided by government and nonprofit agencies

Appendix G

Pap Manual Evaluation Form

We appreciate your comments or suggestions about this manual. Your suggestions will help us continue to make the Pap Screening Manual as useful as possible.

Complete and fax to Professional Development,
NC Breast and Cervical Cancer Control Program, (919) 870-4812.

Date:_____

Name:_____

Organization: _____

1. How much of this manual did you read?

❑ All of it ❑ Most of it ❑ Only a little of it

2. How useful was this manual in developing your cervical screening policies?

3. Please circle the number that indicates how useful each section of the manual was:

Low			High	
1	2	3	4	Introductory pages and table of contents
1	2	3	4	Sect. I – Patient Management and Follow Up of Pap Test Results
1	2	3	4	Sect. I – Algorithms
1	2	3	4	Sect. II – Procedure for Obtaining a Pap Test
1	2	3	4	Sect. III – Cancer Screening Follow Up DHHS Form 1011
1	2	3	4	Section IV – Quality Assurance Recommendations
1	2	3	4	Appendix A – State Lab Bethesda Reporting System
1	2	3	4	Appendix B – Critical Value Notification
1	2	3	4	Appendix C – NC BCCCP Cervical Cancer Screening Policies
1	2	3	4	Appendix D – Qualified Health Care Providers for Evaluation and Treatment of Dysplasia
1	2	3	4	Appendix E – References and Resources

4. For your background and experience, please tell us if you thought this manual was:

❑ Too difficult ❑ Too basic ❑ Just right

5. How can this manual be improved?

6. Do you have suggestions for other program manuals?

7. Do you have any other comments you would like to share?